UNIVERSIDAD COMPLUTENSE DE MADRID
FACULTAD DE MEDICINA

TESIS DOCTORAL

Impacto de las nuevas recomendaciones de la Comisión Internacional en Protección Radiológica en las prácticas intervencionistas

MEMORIA PARA OPTAR AL GRADO DE DOCTOR

PRESENTADA POR

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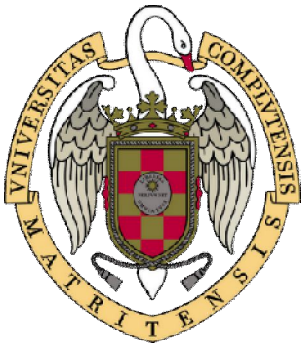
MEMORIA DE TESIS DOCTORAL



Impacto de las nuevas recomendaciones de la Comisión Internacional en Protección Radiológica en las prácticas intervencionistas.

Presentada por: Roberto Mariano Sánchez Casanueva

Director y tutor: Eliseo Vañó Carruana.

A Mariano y Pilar, por el ejemplo de esfuerzo, constancia y sacrificio que siempre han sido. Por estar siempre presentes en cada paso que he dado en mi vida.

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ÍNDICE

ÍNDICE DE FIGURAS

TESIS DOCTORAL EN FORMATO DE PUBLICACIONES

Esta tesis doctoral se presenta en formato de publicaciones, de acuerdo con el punto 3 del artículo 10 del Consejo de Gobierno de la Universidad Complutense de Madrid de 23 de abril de 2015 (BOUC 29/04/15) por que se aprueba la normativa de doctorado y desarrolla el Real Decreto 99/2011 de 28 de enero (BOE 10/02/11) que regula los estudios de doctorado en la Universidad Complutense de Madrid. Dichas publicaciones recogen todos los resultados que han sido obtenidos en los diferentes trabajos de investigación desarrollados con el fin de alcanzar el objetivo fijado para la realización de la tesis.

Publicaciones incluidas en esta tesis.

I.- RM Sánchez, E Vano, JM Fernández, M Moreu and L López-Ibor. Brain radiation doses to patients in an interventional neuroradiology laboratory. American Journal of Neuroradiology en julio de 2014; número 35, páginas 1276–1280.

II.- RM Sánchez, E Vano, JM Fernández, S Rosati y L López-Ibor. Radiation doses in patient eye lenses during interventional neuroradiology procedures. American Journal of Neuroradiology (2016) Mar; 37(3): 402-7.

III.- Roberto M. Sánchez, Eliseo Vano, José M. Fernández and Javier Escaned. Evaluation of a real-time display for skin dose map in cardiac catheterisation procedures. Radiation Protection Dosimetry (2015) Jul;165(1-4):240-3.

IV.- RM Sánchez, E Vano, JM Fernández, X Pifarré, JM Ordiales, JJ Rovira, F Carrera, J Goicolea and A Fernández-Ortiz. Occupational eye lens doses in

interventional cardiology. A multicentric study. Journal of Radiological Protection 36 (2016): 133–143

V.- E. Vano, **R. M. Sánchez** and J. M. Fernández. Estimation of staff lens doses during interventional procedures. Comparing cardiology, neuroradiology and interventional radiology. Radiation Protection Dosimetry (2015), 165: 279-283.

ACRÓNIMOS Y DEFINICIONES.

CA: Coronary angiography.

CBCT: Cone Beam Computed Tomography.

CR: Computed radiography.

CT: Computed Tomography.

CTO: Chronic Total Occlusion.

Cu: Cobre. Metal utilizado en los filtros de los tubos de rayos-X.

DICOM: Digital Imaging and Communication in Medicine.

DOCCACI: Dosimetría y criterios de calidad en cardiología intervencionista.

DSA: Digital subtraction angiography.

Gy: Gray. Unidad de dosis absorbida.

$H_p(0,07)$: Dosis equivalente personal a 0,07 mm de profundidad. Su unidad en el sistema internacional es el Sievert.

$H_p(10)$: Dosis equivalente personal a 10 mm de profundidad. Su unidad en el sistema internacional es el Sievert.

ICRP: International Commission on Radiological Protection.

Kerma: Kinetic Energy Released per Unit of Mass. Es la energía cinética de las partículas cargadas liberada por la radiación indirectamente ionizante que interacciona con la materia. Su unidad en el sistema internacional es el Gy.

$K_{a,i}$: Kerma en aire incidente. No tiene en cuenta la retrodispersión.

$K_{a,e}$: Kerma en aire a la entrada. Es el kerma en aire medido a la entrada de la superficie incluyendo la retrodispersión.

K_R: Kerma en aire en el punto de referencia de entrada en el paciente 15 cm por debajo del isocentro.

kV: Kilovoltios. Utilizado para referirse a la tensión aplicada por los generadores en los tubos rayos-X.

MAV: Malformación arteriovenosa.

OSLD: Optically Stimulated Luminiscence Dosimeter.

ORAMED: Optimization of radiation for medical staff. http://www.oramed-fp7.eu/

PCI: Percutaneous coronary intervention.

PCXMC: A Monte Carlo program for calculating patient doses in medical X-ray examinations. http://www.stuk.fi/palvelut/pcxmc-a-monte-carlo-program-for-calculating-patient-doses-in-medical-x-ray-examinations

PDA: Producto dosis área.

P_{KA}: Producto kerma área. También denominado como producto dosis área o PDA. Definido para medir la cantidad de radiación que sale de un tubo de rayos-X como la integral del kerma en aire en el área del campo de radiación.

PSD: Peak Skin Dose. En procedimientos intervencionistas es la dosis máxima en la piel de los pacientes.

RDSR: Radiation dose structured report.

SDM: Skin Dose Map. Prototipo integrado en un equipo de intervencionismo para la medida de mapas de dosis en la piel de los pacientes.

STUK: Autoridad sobre Seguridad Nuclear y Radiaciones de Finlandia.

Sv: Sievert, unidad de dosis equivalente y dosis efectiva.

TAVI: Transcatheter Aortic Valve Implantation.

TC: Tomografía Computarizada.

XML: Extensible Markup Language.

1. RESUMEN

En el año 2012 la Comisión Internacional de Protección Radiológica publicó el documento número 118 que contenía la "*Declaración sobre las reacciones de los tejidos / Efectos de la radiación tempranos y tardíos en tejidos y órganos – Dosis Umbral para reacción de los tejidos en un contexto en protección radiológica*". En dicho documento se estableció un umbral de dosis de radiación de 0,5 Gy en cerebro o en corazón para producir enfermedad circulatoria. También redujo a 0,5 Gy la dosis umbral en cristalino para producir cataratas. En el caso del cristalino, además la ICRP ha recomendado una reducción del límite de dosis para los trabajadores a 20 mSv/año promediando en periodos de 5 años, sin que se excedan los 50 mSv en un único año. Dicha recomendación ya ha sido incorporada a la normativa europea a través de la directiva 2013/59/EURATOM. En los procedimientos intervencionistas guiados por fluoroscopia, puede ser necesario usar altas dosis de radiación. La dosis recibida en la piel de los pacientes ha sido y sigue siendo objeto de estudio, demostrándose que en los casos más complejos o en pacientes que han requerido sucesivos procedimientos en su tratamiento, se han producido lesiones en la piel de diversa gravedad. En el caso de los trabajadores, el cristalino ha sido también objeto de investigación, observándose mayor probabilidad de desarrollar opacidades en cristalino en los profesionales del ámbito intervencionista. Tras la publicación de la declaración sobre reacciones en tejidos por parte de la ICRP, además de la dosis en la piel de los pacientes, se ha considerado conveniente estimar las dosis que pueden recibir en cerebro o cristalino. En el caso de los trabajadores, es necesario investigar si el nuevo límite de dosis en cristalino puede suponer la necesidad de reforzar la protección para seguir trabajando en condiciones de seguridad. Por otro lado, la evolución de estas prácticas durante los últimos

años, si bien está posibilitado el abordaje de patologías más complejas, requiere utilizar mayores cantidades de radiación, siendo necesaria una evaluación continua de los riesgos radiológicos y de las estrategias de optimización.

Esta tesis doctoral describe la metodología y resultados de la evaluación de las dosis de radiación administradas en cerebro y cristalino a los pacientes sometidos a procedimientos de neurorradiología intervencionista, describe también las ventajas de un programa de cálculo elaborado para estimar la dosis que recibe la piel de los pacientes sometidos a procedimientos de cardiología intervencionista y por último evalúa las dosis recibidas en el cristalino de los profesionales.

En un 40% de los procedimientos terapéuticos de neurorradiología intervencionista estudiados, se impartió una dosis en el cerebro superior a 0,5 Gy, llegando hasta 1,7 Gy en el caso de mayor dosis. Un 16% de los casos terapéuticos de neurorradiología intervencionista resultó con dosis en el cristalino izquierdo mayores de 0,5 Gy, con 2 Gy en el caso de dosis máxima. Debe prestarse especial atención a las dosis recibidas por pacientes que requieren varios procedimientos para tratar su patología y se debe establecer un registro dosimétrico que permita hacer este seguimiento. En cardiología intervencionista, el 1% de los casos (diagnósticos y terapéuticos) superaron los 2 Gy de dosis pico en la piel. La visualización del mapa de dosis en piel en tiempo real durante los procedimientos, permite adaptar el protocolo para evitar altas dosis de rayos-X en la piel. Es necesario tener en cuenta estos datos al valorar la justificación de estos procedimientos e informar adecuadamente a los pacientes para hacer, cuando sea necesario, un seguimiento de las posibles lesiones en cristalino o en la piel. En lo referente a los profesionales, el promedio de la dosis

ocupacional medida sobre el delantal en los especialistas, fue de 46 μSv/procedimiento, que dependiendo de la carga de trabajo, pueden implicar dosis anuales entre 20 y 25 mSv. En patologías complejas de cardiología intervencionista como las angioplastias con oclusión total crónica o en procedimientos estructurales, la dosis ocupacional promedio por procedimiento medida sobre el delantal, fue de 100 μSv. El aumento de la complejidad supone un incremento en el riesgo radiológico que requiere vigilancia sistemática e individualizada de las dosis de radiación en las salas de intervencionismo.

ABSTRACT

In 2012, in report 118, the International Commission on Radiological protection included the "*ICRP Statement on tissue reactions / Early and late effects of radiation in normal tissues and organs - Threshold doses for tissue reactions in tissues in a radiation protection context*". In that document, a threshold dose of 0.5 Gy was established for risks of brain and heart circulatory diseases. The threshold dose for eye lens injure was also reduced. In the case of eye lens, ICRP recommended a reduction of the current dose limit for workers to 20 mSv/year averaged over five years, with less than 50 mSv/year. This recommendation has been currently included in the European legislation in directive 2013/59/EURATOM. In fluoroscopy guided interventional procedures, high radiation doses may be needed. Radiation doses delivered to patients' skin remain a topic of continued investigation in radiation safety and it has been shown that in the most complex procedures or in patients whose treatments require several procedures, radiation doses may cause skin injuries with varying degrees of severity. In case of professionals, the eye lens have been also investigated, and a higher likelihood of developing eye lens opacities has been observed in interventional professionals. Following the ICRP statement on tissue reactions, it was considered necessary to estimate not only the skin dose received by patients, but also the doses received by brain and eye lenses. In the case of workers, it is necessary to investigate if the new dose limit for the lens of the eyes requires new protective measures to ensure the safest working conditions for staff. The evolution of the interventional practices on one hand makes it possible to treat more complex pathologies, but on the other hand requires higher amounts of radiation, which requires an ongoing assessment of the radiological risks and therefore optimization strategies.

This thesis describes the methodology and results of the evaluation of radiation doses delivered to the brain and eye lenses of patients who underwent interventional procedures in neuroradiology; it also describes the advantages of a computational program to estimate patients' skin doses in interventional cardiology and it finally evaluates the eye lens doses in interventionalists.

In 40% of the therapeutic procedures carried out in interventional neuroradiology and studied in this work, brain doses greater than 0.5 Gy were administered, with a maximum dose of 1.7 Gy. 16% of therapeutic procedures of interventional neuroradiology resulted with doses in the left eye lens greater than 0.5 Gy, with a maximum dose of 2 Gy. Special attention must be paid to patients whose pathology requires several procedures and a dosimetric record should be established to carry out this follow-up. In interventional cardiology, in 1% of the cases (diagnostic and therapeutic) peak skin dose was found to be greater than 2 Gy. Real time skin dose mapping technology enables operators to visualize skin dose distribution during procedures and to adapt the protocol so as to avoid high X-ray skin doses. These results must be taken into account for justification purposes; they also provide suitable information to patients, when a follow-up proves necessary in cases of potential eye or skin injuries. With regard to professionals, the average occupational dose measured over the apron was 46 μSv/procedure for the first operator, which depending on the workload, may imply annual doses of 20 and 25 mSv. In complex interventional cardiology pathologies like angioplasties with chronic total occlusions or in some structural procedures, the average occupational dose per procedure over the apron was 100 μSv. Radiological risks that require a systematic and individualized surveillance of radiation doses in interventional laboratories are rising at the same time as the complexity in procedures is increasing.

2. INTRODUCCIÓN

La Comisión Internacional de Protección Radiológica (ICRP en sus siglas en inglés), es un organismo independiente que emite recomendaciones orientadas a minimizar el impacto negativo de las radiaciones ionizantes, sin renunciar a los beneficios que éstas proporcionan. Desde el año 1928 ha publicado más de 132 documentos en todos aspectos de protección radiológica. La ICRP ha promovido el uso del sistema internacional de protección radiológica, el cuál es la base que inspira la legislación en esta materia en la mayoría de los países del mundo. El ámbito médico es para ICRP una de las prioridades a considerar, ya que supone la contribución más importante en dosis colectiva a la población [1]. En particular, las prácticas intervencionistas han sido objeto de estudio ya que, por su complejidad, pueden producir efectos tisulares en piel de los pacientes, así como opacidades en el cristalino de los especialistas [2-5]. En el año 2012, ICRP publicó su documento 118 sobre los efectos de las radiaciones en tejidos y órganos [6], donde se revisan los últimos hallazgos epidemiológicos. Una de las principales novedades ha sido la de reducir los umbrales de dosis de radiación para algunos efectos tisulares (efectos deterministas) como las cataratas en cristalino o alteraciones vasculares en cerebro o corazón. En el caso del cristalino, antes de la publicación ICRP 118 [6], la recomendación establecía una dosis umbral de 5 Gy para la aparición de cataratas [7]. En su última revisión, donde se incluyen los últimos estudios realizados en las poblaciones supervivientes de las bombas atómicas [8-10], de la catástrofe de Chernóbil [11], o estudios en poblaciones de técnicos en radiología [12], dicho umbral se ha reducido a 0,5 Gy. Este documento ICRP 118, también recomienda una reducción del límite de dosis en cristalino de 150 a 20 mSv/año. En el caso del cerebro, las últimas publicaciones [13] han sugerido un umbral de 0,5 Gy para el exceso del riesgo relativo de ictus y también un umbral de 0,5 Gy en corazón para la aparición de enfermedad

cardiovascular. Por otro lado, y en consonancia con los efectos en cerebro, ha crecido la preocupación en sociedades científicas por la aparición de algunos casos de tumores cerebrales en hemisferio izquierdo entre profesionales de cardiología intervencionista [14-16].

En el caso del cristalino, la recomendación del nuevo límite de dosis ocupacional ha sido incorporada por el Organismo Internacional para la Energía Atómica (OIEA) en las nuevas Normas Básicas de Seguridad [17] y posteriormente, otros organismos, como la Comisión Europea, han decidido adoptar el nuevo límite de exposición ocupacional al cristalino de 20 mSv/año en todas las prácticas (con excepción de las situaciones de emergencia) [18].

Es necesario por lo tanto conocer los niveles de dosis de radiación en los principales órganos y tejidos con umbrales bajos de dosis, en los que hay probabilidad de producir un efecto adverso para:

1) minimizar en la medida de lo posible los efectos adversos en los pacientes, asegurando al mismo tiempo el éxito diagnóstico o terapéutico de los procedimientos.
2) adoptar las medidas de protección adecuadas para poder seguir realizando estas prácticas en condiciones de seguridad en el caso de los trabajadores.

2.1. Protección radiológica de los pacientes.

Respecto a la protección radiológica de los pacientes, las recomendaciones de ICRP también se han trasladado a la legislación europea (y posteriormente se deberán transponer a la normativa española). Entre otros requisitos, la nueva directiva europea [18] indica que:

1) la información relativa a la exposición del paciente deberá ser incluida en el informe del procedimiento médico y
2) los países miembros de la Unión Europea deberán establecer, revisar regularmente y utilizar los niveles de referencia para diagnóstico en radiología intervencionista.
3) el médico, el experto en física médica y aquellos nombrados para llevar a cabo los aspectos prácticos de los procedimientos radiológicos, estarán involucrados, según especifiquen los estados miembros, en los procesos de optimización.

Los fabricantes de equipos radiológicos están adaptando sus productos para facilitar el cumplimiento del requisito acerca de la inclusión de la dosis del paciente en el informe radiológico, incorporando indicadores de dosis en la información de la cabecera de las imágenes digitales o en los informes estructurados de dosis de radiación (RDSR en sus siglas en inglés). La industria también ha comenzado a producir nuevos sistemas y dispositivos informáticos para registrar la información dosimétrica en formato digital, tomando como modelo en muchos casos, prototipos desarrollados en institutos de investigación [19-23]. Algunos países europeos han iniciado acciones para establecer valores de referencia para diagnóstico en las prácticas intervencionistas [24-29]. Existen también iniciativas en EE.UU. y a nivel internacional [30]. En España existen ya experiencias previas promovidas por la Universidad Complutense de Madrid y el Hospital Clínico San Carlos en colaboración con la Sociedad Española de Radiología Vascular e Intervencionista (SERVEI) y con la Sección de Hemodinámica de la Sociedad Española de Cardiología (SH/SEC). La SERVEI ha publicado valores de referencia en su página web para algunos tipos de procedimientos frecuentes como la arteriografía de miembros inferiores, el drenaje biliar, la quimioembolización hepática o el stent iliaco [31-33]. También ha publicado datos sobre las dosis ocupacionales de los radiólogos

intervencionistas [34]. Inspirado en esta iniciativa, la SH/SEC ha impulsado el programa "Dosimetría y criterios de calidad en cardiología intervencionista" (DOCCACI) para proponer valores de referencia en angiografía y angioplastia coronaria e investigar las dosis ocupacionales [35].

2.1.1. Dosis en cerebro y en cristalino de los pacientes sometidos a procedimientos de neurorradiología intervencionista.

Gracias a los avances tecnológicos y médicos en neurorradiología intervencionista, es posible abordar patologías más complejas con procedimientos también más complejos que pueden requerir altas dosis de radiación. Por ejemplo, la inclusión en los angiógrafos de las técnicas de adquisición tridimensional en modo de tomografía computarizada de haz cónico (siglas en inglés CBCT), capaz de adquirir imágenes tridimensionales tipo TC, ofrece ventajas para los pacientes en clínica, pero también contribuyen a aumentar las dosis de radiación [36, 37]. Son de especial interés los casos del cerebro y el cristalino, dos de los órganos cuyos umbrales para provocar reacciones tisulares, en concreto enfermedad cerebro vascular y opacidades en cristalino, han sido reducidos a 0.5 Gy en las nuevas recomendaciones de ICRP [6]. Dosis de ese orden de magnitud podrían ser superadas durante procedimientos complejos de neurorradiología intervencionista [38-40], por lo tanto, hay que prestar una atención especial a la optimización de los procedimientos en estos casos. La ICRP también ha indicado que, en el caso de los pacientes pediátricos, las dosis de 1-2 Gy al cerebro en desarrollo, pueden causar trastornos cognitivos y de comportamiento, y los niños tratados antes de los 18 meses, son más susceptibles a sufrir trastornos cognitivos como adultos, tras exposiciones a dosis por encima de 0,1 Gy [6].

En el caso del cristalino, tal y como se ha comentado, la ICRP ha concluido que es más radiosensible de lo inicialmente previsto [6], y es posible producir

opacidades con dosis por debajo de los 0,5 Gy. Hay poca información publicada acerca de las dosis que reciben en cristalino los pacientes que se someten a procedimientos de neurorradiología intervencionista. Moritake et al. [41] han publicado valores de dosis promedio en ojos de 0,38 Gy, con dosis máximas de 2,1 Gy durante embolizaciones cerebrales, cuatro veces el umbral recomendado por la ICRP. Sandborg et al. [40] han publicado dosis medias y máximas en cristalino de 0.071 y 0.52 Sv respectivamente (en el caso de los rayos-X la dosis equivalente en Sv es numéricamente igual a la dosis absorbida en Gy), también durante embolizaciones cerebrales. La variabilidad en la poca información disponible indica la necesidad de más investigación en los riesgos para el cristalino en estas prácticas médicas.

Por lo tanto, aunque estos procedimientos conllevan un beneficio neto para los pacientes, es necesario conocer el orden de magnitud de la dosis de radiación administrada a los pacientes para ayudar a los neurorradiólogos intervencionistas a gestionar adecuadamente los riesgos derivados del uso de radiaciones ionizantes, de modo que puedan proporcionar información y aconsejar adecuadamente a sus pacientes durante un seguimiento de posibles lesiones radioinducidas.

Para cumplir la normativa nacional [42], los equipos de neurorradiología intervencionista deben registrar la dosis administrada a los pacientes. Éstos suelen proporcionar el producto kerma área (P_{KA}) y el kerma en aire en el punto de referencia de entrada en el paciente (15 cm por debajo del isocentro) (K_R) [43], pero no la dosis en los órganos del paciente. El P_{KA} se define como la integral del kerma en el área del campo de radiación [44], también comúnmente denominada producto dosis área (PDA). La dosis en órganos, como el cerebro o el cristalino, es la magnitud relevante para estudiar los posibles efectos biológicos, su relación con los indicadores P_{KA} y K_R no es directa, y su

estimación requiere cálculos individuales realizados por un Radiofísico Hospitalario.

En esta tesis doctoral se presentan valores de dosis administradas en cerebro y cristalino de pacientes sometidos a procedimientos de neurorradiología intervencionista, registradas en el Hospital Clínico San Carlos de Madrid. Las dosis en cerebro se han estimado usando un modelo matemático de maniquí antropomórfico y registrando parámetros geométricos y dosimétricos de los procedimientos clínicos. Las dosis en cristalino se han medido usando dosímetros de luminiscencia estimulada ópticamente (siglas en inglés OSLDs). Se ha analizado la relación de otras variables con la dosis en cerebro y cristalino tales como el P_{KA}, el K_R y la colimación. La contribución de las series de CBCT, tanto en dosis en cerebro como en cristalino, también ha sido investigada.

2.1.2. Optimización de la dosis en la piel de los pacientes en cardiología intervencionista.

Por otro lado, es bien sabido que durante los procedimientos intervencionistas es posible recibir altas dosis de radiación en la piel [2]. La ICRP recomienda estimar la dosis en piel para aquellos pacientes que pudieran haber recibido dosis altas y, en el caso de determinar una alta dosis en la piel, realizar un seguimiento de las posibles lesiones [2, 45]. También se ha pronunciado de igual modo la Sociedad Norteamericana de Radiología Intervencionista [46]. Dependiendo de la dosis pico en piel (PSD en sus siglas en inglés) recibida por el paciente, pueden producirse lesiones con distinto grado de severidad, desde un eritema transitorio (2-5 Gy de dosis pico), hasta la descamación húmeda y necrosis (más de 15 Gy de dosis pico en piel) [47]. En algunos casos las lesiones en piel son efectos secundarios inevitables de procedimientos destinados a salvar la vida del paciente, en tales casos, el

conocimiento de la dosis recibida en la piel del paciente es necesaria para proporcional las recomendaciones adecuadas para tratar la lesión que podría desarrollar, o en casos necesarios, un seguimiento de las posibles lesiones en piel. En otros casos, las lesiones en piel podrían ser evitadas si los profesionales (convenientemente entrenados), tuvieran información sobre la distribución de dosis en la piel del paciente, así como información sobre la dosis recibida en intervenciones recientes. La nueva directiva 2013/59 de la Comisión Europea [18] requiere que la información relativa a la exposición del paciente sea incluida en el informe del procedimiento médico. La ICRP recomienda investigar aquellos pacientes que hayan recibido en la piel una dosis pico de más de 3 Gy, y determinar si es necesario realizar un seguimiento de las posibles lesiones en la piel [2]. En las prácticas intervencionistas, las magnitudes radiológicas que suelen registrarse son el P_{KA}, el K_R, el tiempo de fluoroscopia, el número de series y el número de imágenes adquiridas. Ninguno de estos indicadores está relacionado directamente con la dosis pico en piel [48]. Los equipos modernos muestran en los monitores de visualización de imagen, el K_R y el P_{KA} en tiempo real durante las intervenciones. Pero es difícil para los intervencionistas optimizar la distribución de la dosis en piel a partir de estas magnitudes. Se han utilizado películas lentas o placas fotoestimulables de radiología computarizada (CR) para medir la dosis en piel [49-52], pero se requieren muchos recursos tanto materiales como humanos para su utilización rutinaria. Una solución propuesta es la de instalar ordenadores con programas dedicados para calcular la dosis pico en piel en tiempo real [53-57].

Uno de los objetivos de esta tesis es la de evaluar un prototipo para la estimación de la dosis en la piel en tiempo real, instalado en un equipo de rayos-X para cardiología intervencionista y su utilidad en la optimización de los procedimientos.

2.2. Protección radiológica de los trabajadores implicados en prácticas intervencionistas.

En el caso de los trabajadores, hay publicaciones acerca de los niveles de radiación en las prácticas intervencionistas. El programa europeo ORAMED (Optimization on RAdiation protection for MEDical staff") [58] ha obtenido valores de dosis en extremidades y cristalino en diversas prácticas médicas de radiología y medicina nuclear concluyendo que, en radiología y cardiología intervencionista, los niveles de radiación en cristalino podrían superar el nuevo límite de dosis ocupacional recomendado si no se toman medidas de protección adecuadas. Otros autores han estudiado el problema de la dosis ocupacional en radiología y cardiología intervencionistas [59-63] coincidiendo en el orden de magnitud de los valores medidos y también en la gran variabilidad entre distintos facultativos dependiendo del tipo de procedimientos abordados y los distintos medios de protección utilizados. Por otro lado, las técnicas intervencionistas evolucionan con mucha rapidez, abordando nuevas patologías más complejas que implican mayores dosis de radiación tanto para los pacientes como para los trabajadores, como por ejemplo las angioplastias en oclusiones totales crónicas o los implantes valvulares aórticos percutáneos (TAVI en sus siglas en inglés) en cardiología intervencionista. Es necesaria por lo tanto, una evaluación de las dosis a los profesionales (a ser posible en el ámbito nacional) para ser comparadas con los resultados en otros países del entorno y los nuevos límites ocupacionales así como evaluar el impacto de la complejidad de los procedimientos en las dosis que reciben los profesionales.

La mejor forma de investigar las dosis de radiación recibidas por los trabajadores de cardiología intervencionista sería analizar los registros de dosis personal, pero la medida de la dosis en cristalino requiere de dosímetros especialmente diseñados para ser llevados cerca de los ojos. La ICRP

recomienda llevar un segundo dosímetro sobre el delantal para estimar la dosis de radiación en órganos no protegidos (como el cristalino) [2-45], pero muy a menudo, los trabajadores llevan un único dosímetro bajo el delantal o incluso, a veces, el uso del dosímetro personal es inadecuado o escaso entre los cardiólogos intervencionistas [45,64-66]. Estos factores hacen difícil en la práctica estimar las dosis recibidas en cristalino por estos profesionales. Es por ello que se recomienda llevar a cabo investigaciones adicionales consistentes en simulaciones matemáticas o en maniquíes y realizar medidas durante procedimientos clínicos para complementar el conocimiento de las dosis ocupacionales [59, 60, 67-69]. Los resultados obtenidos apuntan a que, dependiendo del nivel de protección y la carga de trabajo, muchos intervencionistas podrían superar el límite de dosis ocupacional para el cristalino, con una probabilidad no despreciable de sufrir cataratas radioinducidas tras muchos años de trabajo sin protección adecuada.

En esta tesis doctoral se presentan las medidas de dosis equivalente personal $H_p(10)$ [70] medida en solapa, sobre el delantal, en procedimientos de cardiología, neurorradiología y radiología intervencionistas. También se ha medido la dosis ocupacional, para procedimientos de cardiología intervencionista, en cinco hospitales de España localizados en Cataluña (1), Extremadura (1), Andalucía (1) y Madrid (2), para ser comparadas con el nuevo límite de dosis equivalente en cristalino de 20 mSv/año.

3. OBJETIVOS

Los objetivos de este proyecto de tesis doctoral abarcan la investigación de aspectos en el ámbito de la radiología y cardiología intervencionistas referentes a:

1) Evaluar las dosis de radiación administradas en cerebro y cristalino a los pacientes sometidos a procedimientos de neurorradiología intervencionista, dos de los órganos cuyo umbral de efectos tisulares (deterministas) inducidos por las radiaciones ionizantes han sido revisados en las últimas recomendaciones de la ICRP.
2) Evaluar una herramienta de "software" para estimar la dosis que reciben en piel los pacientes sometidos a procedimientos de cardiología intervencionista e investigar su utilidad en la optimización de los procedimientos.
3) Evaluar las dosis de radiación en cristalino a los profesionales de distintas disciplinas intervencionistas y comparar los resultados con el nuevo límite de 20 mSv/año incluido en la nueva directiva europea. En el caso de la cardiología intervencionista se incluye un estudio en cinco centros del ámbito nacional.

4. MATERIALES Y MÉTODOS

4.1. Estudio de dosis a los pacientes. Dosis en cerebro en pacientes sometidos a procedimientos de neurorradiología intervencionista.

Se han recopilado secuencialmente casos de pacientes sometidos a angiografía y/o embolizaciones cerebrales durante un periodo de 3 meses realizados en el Hospital Clínico San Carlos (Madrid, España). Se han excluido intervenciones a nivel de carótida y cervicales. Todos los procedimientos fueron realizados en una sala dedicada a procedimientos de neurorradiología equipada con un equipo de rayos-X biplano modelo Allura FD 20/10 (Philips). Los arcos frontal y lateral poseen respectivamente detectores de imagen planos de 48 y 25 cm de diagonal, de modo que cuando la cabeza del paciente está colocada en el isocentro con los detectores de imagen a unos 10 cm de ésta y sin aplicar colimación al haz, el detector frontal cubre un campo de 27x27 cm^2 y el lateral unos 14x14 cm^2 en el isocentro. Ambos arcos tienen instalados a la salida de sus tubos de rayos-X, cámaras de transmisión para medir el producto kerma área P_{KA} (también llamado producto dosis área o PDA) administrado a los pacientes, el cual es incluido en los informes de dosis que proporciona el equipo de rayos-X. En la mayoría de los procedimientos, las series de sustracción digital (DSA) son adquiridas a 2 imágenes/segundo durante los primeros 5 segundos y a 1 imagen/segundo durante el resto del tiempo. El sistema tiene la capacidad de utilizar dos tipos de adquisición de imagen tridimensional en modo CBCT usando el arco frontal. Dependiendo del modo de CBCT seleccionado, el sistema adquiere o bien 313 imágenes (baja dosis) o bien 622 imágenes en una rotación en arco de 240º con el tamaño de campo 48 cm. Independientemente del modo CT seleccionado, el sistema siempre ajusta la misma técnica: 120 kV, 250 mA, 5 ms (tiempo de pulso) y una filtración añadida de 0,4 mm de cobre más 1 mm de aluminio. En la mayoría de los procedimientos terapéuticos en

nuestro centro, se realiza al menos una serie de CBCT de alta dosis, que aproximadamente equivale (en P_{KA}) a unas 38 imágenes de sustracción digital (protocolo cerebral del equipo de este centro). En algunos procedimientos también se adquirió una serie para su reconstrucción en 3 dimensiones con la técnica de adquisición rotacional. Esta última técnica, es similar a la adquisición CBCT, utilizando menos dosis siendo necesario inyectar contraste para visualizar los vasos sanguíneos.

Para calcular las dosis en cerebro se utilizó el programa PCXMC 2.0 Rotation (STUK, Finlandia)[1] [71]. Este programa calcula dosis equivalente en órganos y estima dosis efectivas en un modelo matemático de maniquí antropomórfico de diferentes edades y tamaños (a pesar de las limitaciones que tiene estimar esta magnitud radiológica en el caso de pacientes). El programa realiza simulaciones con el método de Monte Carlo del transporte de la radiación a través del maniquí antropomórfico a partir de los indicadores de la dosis que recibe el paciente (producto dosis área, kerma de entrada, etc.) y de otros parámetros físicos y geométricos de las distintas proyecciones de rayos-X (kilovoltios, filtración añadida, ángulos del arco, etc.) Todos los cálculos han sido realizados en el maniquí estándar correspondiente a un adulto de 179 cm de altura y 73 kg de peso con los datos anatómicos incluidos en el modelo matemático de Cristy-Eckerman [72].

Se ha registrado información detallada acerca de los parámetros físicos y geométricos para cada evento de radiación (a nivel de serie) en el equipo de rayos-X y extraída con ayuda de los ingenieros de servicio de Philips. En esta información están incluidos los ajustes de generador y tubo como tensión, corriente, tiempo, filtración añadida, colimación del haz y angulación del brazo

[1] http://www.stuk.fi/palvelut/pcxmc-a-monte-carlo-program-for-calculating-patient-doses-in-medical-x-ray-examinations

para todas las series de fluoroscopia y sustracción digital, así como el P_{KA} y el kerma en el punto de referencia de entrada en el paciente (K_R), que fueron validados por un físico médico y, en el caso del arco frontal, corregido por la atenuación de la mesa y la colchoneta.

El equipo de rayos-X utilizado tiene distancias desde el foco al isocentro de 81 y 76.5 cm para los arcos frontal y lateral respectivamente. La posición de la mesa de tratamiento respecto del arco es registrada por el equipo, por lo tanto, se tomó la suposición de que la cabeza del paciente estaba siempre centrada en el isocentro (condición esencial en un equipo biplano y también durante las adquisiciones CBCT). En los tubos de rayos X utilizados, los ángulos anódicos son de 11º y 9º para el frontal y el lateral respectivamente y se ha supuesto una filtración inherente de 2,5 mm de aluminio. Se ha estudiado la correlación entre las dosis en cerebro calculadas y los indicadores de dosis a pacientes, P_{KA} y K_R y también con la colimación del haz.

4.2. Estudio de dosis a los pacientes. Dosis en cristalino en pacientes de neurorradiología intervencionista.

En este estudio se han seleccionado aleatoriamente casos de angiografía cerebral (n = 5) y procedimientos terapéuticos (n = 31). Los procedimientos terapéuticos consistieron en embolizaciones de malformaciones arteriovenosas (MAV) (n = 13) principalmente de los grados IV y V (Spetzler-Martin) [73], fistulas (n = 2); y aneurismas (n = 16). Todos los procedimientos fueron realizados en la sala de neurorradiología equipada con la unidad de rayos-X Allura FD 20/10 biplano (Philips, Best, Holanda) del Hospital Clínico San Carlos (Madrid) descrito en la sección 0, al igual que los protocolos de adquisición de sustracción digital y CBCT.

Se han estimado las dosis de radiación en cristalino midiendo el kerma de entrada en superficie ($K_{a,e}$) con dosímetros de luminiscencia estimulada ópticamente (siglas en inglés OSLD). Para cada paciente, se colocaron 2 sobre los párpados de los pacientes tal y como muestra la figura 1. Los OSLDs utilizados fueron el modelo nanodot (Landauer, Glenwood, Ilinois). Se componen de pequeños discos de 4 mm de diámetro de material luminiscente (Al_2O_3:C), los cuales forman el área activa, envuelto en un protector plástico opaco de 10 × 10 × 2 mm^3. Su pequeño tamaño lo hace adecuado para colocarlo cerca de los ojos. Los OSLDs han sido usados en distintas situaciones clínicas [74-76], pero se debe prestar una atención especial a las limitaciones debidas a la dependencia de su respuesta al ángulo de incidencia del haz y a la energía de la radiación.

Figura 1. 3 Dosímetros OSLD sobre los párpados de una paciente "D" e "I" y también en el centro "C".

Durante los procedimientos de neurorradiología, la calidad del haz de rayos-X puede cambiar con los ajustes de la tensión del generador (kV) y la filtración añadida. Los kV del generador son ajustados por el sistema automático de dosis en el detector de panel plano dependiendo del espesor y densidad del tejido del paciente, que en el caso del protocolo programado en el equipo Allura, los kV son generalmente constantes en torno a 80 kV. La filtración puede cambiar dependiendo del modo de operación seleccionado desde 0.1 mm de cobre (Cu) más 1 mm de aluminio (Al) para el modo de sustracción digital, hasta 0.9 mm Cu más 1 mm Al para el modo de fluoroscopia de baja dosis. Los OSLDs han sido calibrados con haces de rayos-X estándar en el Centro Nacional de Dosimetría (Valencia, España), laboratorio acreditado, y también con los haces de rayos-X del equipo de intervencionismo. Con los haces del equipo de intervencionismo entre 70 y 80 kV para una misma filtración, la diferencia del factor de calibración fue de un 6%, mientras que para las distintas filtraciones las diferencias medidas fueron del 16%. La incertidumbre resultante de la respuesta de los OSLDs con la variación de los kV (6%) fue considerada como aceptable, pero el efecto de las distintas filtraciones (16%) debía ser corregido. Para minimizar la influencia de las distintas filtraciones en la respuesta de los OSLDs, se usó la información incluida en el informe de la dosis de radiación de cada paciente acerca del P_{KA} tal y como se explica a continuación. Los equipos modernos de intervencionismo proporcionan el P_{KA} tanto en los informes de dosis de los pacientes como en la información de cabecera DICOM y puede ser utilizado como indicador de dosis, siempre que se haya sido adecuadamente verificado. En este caso el medidor de P_{KA} tenía una desviación de -10% que ha sido corregida en todos los pacientes. Nuestro equipo de rayos-X emite informes de dosis recibida por los pacientes que incluye la fracción de P_{KA} de fluoroscopia (con alta filtración añadida) y de sustracción digital (con baja filtración añadida). Esta información fue usada para calcular un factor de

calibración corregido para cada procedimiento, combinando los factores de calibración para fluoroscopia y sustracción digital proporcionalmente a la fracción de P_{KA} de fluoroscopia y de sustracción. Una vez que el factor de calibración ha sido estimado para cada procedimiento, las lecturas de OSLDs fueron convertidas a $K_{a,e}$.

En lo relativo a la dependencia angular, ésta ha sido medida para las calidades de haz utilizadas en este estudio, resultando ser en el peor de los casos (incidencia de 90º y baja energía) de un -15% y de un -3% para el caso de incidencia a 90º y haces con alta filtración añadida.

Junto con el $K_{a,e}$ en los ojos, fueron registrados otros parámetros relevantes como el K_R, el tiempo de fluoroscopia, el número de series de sustracción y CBCT y el número de imágenes.

Para medir la contribución de dosis en ojos durante las series de CBCT se realizó una simulación con un maniquí. Se colocó sobre la mesa un maniquí antropomórfico modelo Rando (The Phantom Laboratory, Salem, New York), centrando la cabeza del maniquí en el isocentro y colocando OSLDs en sus ojos. La dosis en ojos fue medida en los dos modos de operación CBCT, baja dosis y alta dosis, ambos modos de operación han sido descritos en la sección 0. Se han estimado los factores de calibración para los OSLDs para la calidad de haz de CBCT.

Se ha realizado un análisis de regresión lineal entre el kerma de entrada en ojos y otros indicadores de dosis con el paquete estadístico SPSS V12 (IBM, Armonk, New York).

Un comité de ética independiente aprobó este estudio bajo el título “Riesgo radiológico en procedimientos guiados por fluoroscopia” (código B-09/20).

4.3. Optimización de dosis a los pacientes. Verificación de un sistema en tiempo real para estimar la dosis pico en piel durante procedimientos de cardiología intervencionista.

Se instaló temporalmente el prototipo Skin Dose Map (SDM) (Philips, Best, Holanda) en una sala de cardiología intervencionista equipada con un Philips Allura FD 10. El sistema SDM captura desde la unidad de rayos-X, todos los datos relevantes tales como la colimación de haz, filtros en cuña, ángulos del arco en C, posición de la mesa etc., para proyectar el K_R en una superficie cilíndrica, simulando el paciente situado sobre la mesa de exploraciones. El prototipo evaluado, no aplicaba corrección por atenuación de la mesa ni retrodispersión. El dispositivo mostraba a los cardiólogos, en una pantalla situada en la sala de operaciones, la distribución superficial de dosis proyectada en el cilindro y el K_R máximo teniendo en cuenta el solapamiento de distintas proyecciones (figura 2). Si el valor del K_R en la proyección alcanzaba 2 Gy, una advertencia en rojo aparecía en la esquina superior derecha de la pantalla. El K_R fue medido por una cámara de transmisión instalada a la salida del tubo. Esta cámara de transmisión proporcionaba el P_{KA} en el panel de control y en los monitores de visualización y lo transfiere al informe de dosis del paciente. Un Radiofísico Hospitalario, siguiendo las recomendaciones nacionales [42], validó estos valores. Los cardiólogos podían ver el mapa de dosis en tiempo real con un tamaño de píxel de 5×5 mm^2 en una pantalla de 10'' anexa a los monitores de la sala. La matriz de dosis puede ser exportada en formato XML para ser analizada.

Para realizar la validación, se colocó un absorbente de cobre en el detector de imagen. Se colocó una película radiocrómica XR RV3 (Ashland) sobre la mesa del paciente inicialmente a 61,5 cm del foco de rayos-X, es decir en el plano del punto de referencia de entrada al paciente en este arco. Además se

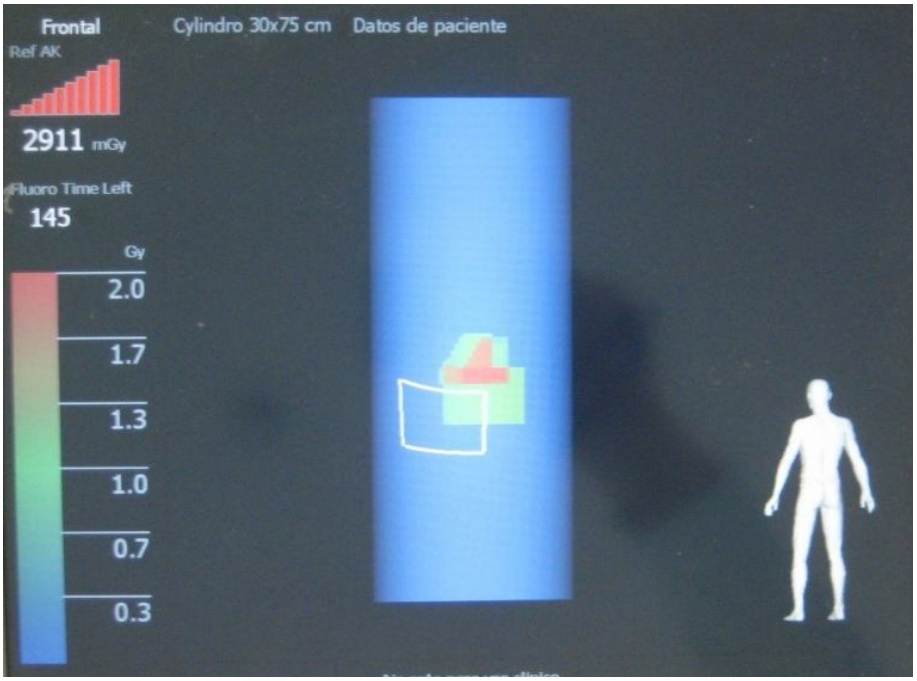

Figura 2. Pantalla del prototipo del sistema Skin Dose Map mostrando una representación del mapa de dosis y el valor de la dosis pico en piel.

adhirieron a la película cuatro pares de OSLDs. Tanto los OSLDs como la película radiocrómica fueron calibrados con la calidad de haz utilizada durante el experimento, referenciados a una cámara de ionización Radcal 20×60 (Radcal Corp). Sobre la película, fue colocado un dosímetro Unfors Xi (Raysafe) para medir el kerma en aire incidente sin retrodispersión ($K_{a,i}$). Los detectores fueron irradiados modificando la posición de la mesa (lateral y verticalmente), el ángulo del arco en C y la colimación. La calidad de haz también fue variada cambiando el espesor del maniquí de cobre - de 4 a 6 mm - situado en el detector de imagen. Para acumular suficiente dosis en la película radiocrómica (> 1 Gy), se irradiaron los detectores usando el modo de cine (alta tasa de dosis) sin filtración añadida. El sistema de control automático de dosis ajustó la tensión del generador entre 79 y 95 kV. La distancia entre dosímetros y el cobre fue suficiente para evitar retrodispersión. El $K_{a,i}$ medido por los dosímetros fue

comparado con el estimado por el prototipo SDM. Se analizaron las distribuciones de dosis con el software ImageJ.

Durante el tiempo que el prototipo estuvo instalado en la sala de cardiología intervencionista (unos 6 meses), se registraron un conjunto de 374 pacientes en el sistema. Se ha investigado la correlación entre el K_R y el P_{KA} con el $K_{i,a}$ máximo proporcionado por el SDM (para ser asimilado como PSD).

4.4. Estudio de dosis a profesionales. Dosis ocupacionales en cristalino en cardiología intervencionista. Un estudio multicéntrico.

El grupo multicéntrico y multidisciplinar DOCCACI (acrónimo de DOsimetría y Criterios de CAlidad en Cardiología Intervencionista) fue formado para investigar las dosis de radiación recibidas por pacientes y profesionales en cardiología intervencionista [77, 78]. Cinco hospitales pertenecientes a este grupo y provinientes de Cataluña, Extremadura, Andalucía y Madrid (2), acordaron medir los valores de dosis equivalente personal $H_p(10)$ sobre el delantal en sus respectivos hospitales, en un total de 10 salas de hemodinámica. Algunos de estos centros son hospitales universitarios con hemodinamistas en formación. Las dosis personales han sido medidas con dosímetros electrónicos de lectura directa en cardiólogos, personal de enfermería y otros profesionales como técnicos o anestesistas. Los participantes usaron el sistema DoseAware (Philips, Best, Holanda), consistente en pequeños detectores de estado sólido de 3,5 × 3,5 cm, diseñados para medir dosis personal en salas de intervencionismo [79]. Siguiendo recomendaciones de ICRP, las lecturas de estos dosímetros llevados sobre el delantal (figura 3), y se usaron para estimar la dosis en cristalino (sin considerar la protección de las gafas plomadas en el caso en que éstas fueran utilizadas) [2, 45].

Figura 3. Dosímetros electrónicos colocados en la solapa de los profesionales y en el arco en C.

Se ha estudiado la correlación entre la dosis en cristalino y los valores de $H_p(10)$ medidos sobre el delantal por parte de varios investigadores [80-83]. Esta correlación puede verse afectada por distintas variables como, por ejemplo, la calidad del haz, la respuesta angular del dosímetro, la posición del operador, el ángulo del arco, el uso de gafas de protección u otros blindajes no estructurales (mamparas suspendidas del techo). Todas estas variables provocan que la dispersión entre los resultados de estas magnitudes sea alta, pero en promedio, los valores de $H_p(10)$ y $H_p(0,07)$ medidos fuera del delantal, tienden a sobreestimar la dosis en cristalino y pueden ser interpretados como una aproximación conservadora, práctica y pragmática en protección operacional para cardiología intervencionista. Los dosímetros electrónicos se comunican inalámbricamente con una estación base que registra las lecturas de tasa de dosis y dosis equivalente personal acumulada $H_p(10)$ cada segundo. Los valores pueden ser mostrados en tiempo real durante las intervenciones en un monitor colocado dentro de la sala de hemodinámica. La pantalla estuvo inicialmente oculta para evitar influir en los hábitos de trabajo y de protección de los

cardiólogos intervencionistas. La unidad de rayos-X proporciona informes de la dosis de los pacientes incluyendo la fecha, hora de inicio y fin de procedimiento y la hora de cada serie de adquisición de cine, que permiten identificar las dosis ocupacionales recibidas en cada procedimiento y relacionarlas con las dosis a los pacientes. En cada procedimiento, se colocaron dosímetros personales en la solapa sobre el delantal y uno de los dosímetros fue colocado en la parte inferior del arco en C, formando aproximadamente un ángulo de 45º con la horizontal como se muestra en la figura 3. La medida de la dosis dispersa en el arco en C puede asimilarse a una estimación conservadora de la dosis de radiación dispersa acumulada por los operadores en cada procedimiento, en un caso muy desfavorable y sin protección adicional [84]. El fabricante de los dosímetros certifica una linealidad de la respuesta < 20% entre 40 $\mu Sv \cdot h^{-1}$ y 300 $mSv \cdot h^{-1}$, una variación con la energía < 20% entre N-40 y N100 y una dependencia angular < 30% para ángulos menores de 50º. El funcionamiento de estos dosímetros ha sido verificado con haces pulsados en salas de intervencionismo y diferencias menores de 15% en dosis acumulada frente a dosímetros de termoluminiscencia fueron considerados aceptables [85].

En uno de los centros, y para un número limitado de procedimientos, la dosis dispersa fue medida también en el lado izquierdo-externo de las gafas de protección con pequeños dosímetros OSLD (1 × 1 × 0,2 cm) modelo nanodot (Landauer Inc). Estos dosímetros han sido probados para medida de dosis ocupacionales en salas de intervencionismo [86]. Gracias a su pequeño tamaño, pueden ser fácilmente colocados en las gafas de protección. Estos dosímetros fueron calibrados para medir $H_p(0,07)$ en el laboratorio secundario acreditado del Institut de Tècniques Energètiques (Barcelona, España).

El valor de $H_p(10)$ sobre el delantal fue medido durante angiografías coronarias (CA) y angioplastias (PCI) (con y sin angiografías previas). En uno

de los centros, también fueron medidas las dosis en pacientes y profesionales durante angioplastias con oclusión total crónica (CTO), procedimientos valvulares incluyendo reposición de válvulas y cierre de fugas, otros procedimientos estructurales como prótesis aórticas (TAVI), cierre de foramen oval o interventricular y procedimientos en electrofisiología como marcapasos y ablaciones. En cada centro, las dosis ocupacionales fueron medidas secuencialmente sin ningún criterio de selección de los procedimientos. Se registró información relacionada con la vía de abordaje (femoral o radial) así como el P_{KA} administrado a los pacientes. Los participantes declararon usar la mampara plomada regularmente.

4.5. Estudio de dosis a profesionales. Dosis ocupacionales en cristalino. Comparando cardiología, neurorradiología y radiología intervencionista.

De nuevo se han utilizado dosímetros electrónicos DoseAware llevados por los profesionales sobre el delantal, en el bolsillo del operador al nivel del tórax. Todas las salas de intervencionismo del Hospital Clínico San Carlos de Madrid incluidas en este estudio fueron Philips Allura, tres salas modelo FD10 en cardiología, una sala con el modelo FD 20/10 (biplano) en neurorradiología y una sala modelo FD20 en radiología intervencionista. Al igual que en el apartado anterior, también se colocó un dosímetro en el arco para estimar el nivel de radiación dispersa en la sala. También fueron registrados indicadores de la dosis a los pacientes como el P_{KA} para analizar su correlación con los valores de dosis dispersa en el arco y en los profesionales. En total han sido registrados 204 procedimientos de cardiología intervencionista, 274 de neurorradiología y 220 procedimientos de radiología intervencionista. Los profesionales que participaron estaban en posesión de la acreditación de

segundo nivel en protección radiológica y hacen uso regular de medidas de protección como el uso de mampara plomada, salir de la sala durante las adquisiciones de sustracción digital o ambas.

5. RESULTADOS Y DISCUSIÓN INTEGRADORA

Los principios en los que se basa el actual sistema de protección radiológica son la justificación, la optimización y la limitación. En el caso de los pacientes sometidos a procedimientos médicos con radiaciones ionizantes, solamente se aplicarían los principios de justificación y optimización. El principio de limitación no es aplicable a pacientes, ya que se les impartirá la dosis necesaria para realizar y finalizar el procedimiento con éxito siempre y cuando esté debidamente justificado. Para una adecuada justificación de los procedimientos es necesario evaluar la relación riesgo beneficio para el paciente y el detrimento en los profesionales, y por lo tanto necesitamos conocer las dosis de radiación que se administran tanto a los pacientes, como las que reciben los profesionales implicados. Las nuevas recomendaciones de la ICRP [6] nos advierten sobre la probabilidad de contraer enfermedad circulatoria en cerebro y corazón con dosis umbrales a partir de 0,5 Gy. También actualiza la dosis umbral para producir opacidades en cristalino, reduciéndola también a 0,5 Gy. En los **trabajos I (**Brain radiation doses to patients in an interventional neuroradiology laboratory **)** y **II (**Radiation doses in patient eye lenses during interventional neuroradiology procedures) se evalúan las dosis en cerebro y cristalino que reciben los pacientes sometidos a procedimientos de neurorradiología intervencionista, obteniendo valores de dosis promedio de cierta importancia. En el caso del cerebro, en los procedimientos terapéuticos de la muestra analizada (N=38), en un 40% de los casos, la dosis media en cerebro superó la dosis umbral de 0,5 Gy. La dosis promedio fue de 0,5 Gy y la dosis máxima de 1,7 Gy. El valor de dosis promedio en cerebro registrado para las embolizaciones resultó muy similar al valor publicado por Thierry-Chef et al. [38] en el caso de usar haces poco colimados, indicando una posible vía para optimizar los procedimientos. La correlación entre las dosis en cerebro y los indicadores de dosis que proporciona el equipo de rayos-X, el P_{KA} y el K_R,

resultaron en un coeficiente de correlación de 0,93 y 0,95 respectivamente. En este caso, ambos indicadores podrían ser utilizados para estimar las dosis en cerebro con un factor de corrección multiplicativo. En el caso del cristalino, en la muestra analizada para procedimientos terapéuticos (N=31), un 16% de los casos superó el umbral de 0,5 Gy en el cristalino izquierdo del paciente. La dosis promedio resultó ser de 0,32 Gy con dosis máxima (recibida en un único procedimiento) de 2,0 Gy. Sandborg et al. [40] han publicado una dosis promedio en cristalino de 71 mGy en una muestra de embolizaciones cerebrales con un P_{KA} promedio de 190 $Gy \cdot cm^2$. En la muestra de embolizaciones en este estudio, la dosis promedio resultó ser de 203 $Gy \cdot cm^2$ muy similar a la de Sandborg et al. [40] pero las dosis en cristalino fueron mucho mayores, indicando que hay margen para la optimización, en particular en el uso de la colimación. En este caso, el coeficiente de correlación entre la dosis en el cristalino izquierdo - el más afectado - y el P_{KA} que proporciona el equipo, fue de 0,63, siendo más incierto estimar la dosis en cristalino a partir de este indicador. En el caso del cristalino, la colimación del haz influye de un modo más determinante que en el cerebro a la hora de estimar las dosis.

Para optimizar los procedimientos será necesario conocer las dosis que reciben los pacientes y en algunos casos serán necesarias herramientas para estimar las dosis en órganos. Este es el caso del cristalino en neurorradiología tal y como se ha visto en el **trabajo II** (Radiation doses in patient eye lenses during interventional neuroradiology procedures) o de la piel, en cardiología intervencionista. En el **trabajo III** (Evaluation of a real-time display for skin dose map in cardiac catheterisation procedures) se ha validado una de estas herramientas para estimar la dosis pico en piel en procedimientos de cardiología intervencionista y ayudar así a los facultativos, a optimizar las dosis de los pacientes. Esta herramienta estima la dosis en piel con precisión suficiente (20%) para crear alertas en tiempo real y permitir cambiar la orientación del haz

en caso necesario para evitar lesiones graves en la piel de los pacientes. Otros autores [53-57] han publicado evaluaciones de otros sistemas para medir la PSD concluyendo diferencias en la estimación de la PSD del 8-20%. En el **trabajo III** (Evaluation of a real-time display for skin dose map in cardiac catheterisation procedures) se presenta el análisis de una muestra de 374 casos de cardiología intervencionista (diagnósticos y terapéuticos), en la que se observó que un 1% de los casos superaron el umbral de 2 Gy de dosis pico en la piel, susceptible de producir lesiones. El coeficiente de correlación entre el K_R y la dosis en piel resultó ser de r^2=0,7, encontrándose casos con K_R que difieren entre sí un 7%, que resultaron en dosis pico en piel que difirieron en un 250%, demostrando que la dosis pico en piel no puede ser estimada con suficiente precisión a partir de los indicadores K_R o P_{KA} y por lo tanto la necesidad de estas herramientas para su correcta determinación en la práctica clínica. Esta herramienta para calcular la dosis pico en la piel de los pacientes, puede ser también adaptada a otras disciplinas intervencionistas como la neurorradiología o la radiología intervencionistas, y sería deseable en un futuro, plantear la estimación de las dosis en otros órganos calificados recientemente por ICRP como especialmente radiosensibles como el corazón, cerebro y el cristalino.

Otro aspecto relevante en la seguridad radiológica de las prácticas intervencionistas es la dosis a los profesionales, en particular las dosis en cristalino y su bajo límite de dosis actualizado recientemente por ICRP a 100 mSv en 5 años (es decir, 20 mSv/año), con un máximo de 50 mSv/año. En los **trabajos IV (**Occupational eye lens doses in interventional cardiology. A multicentric study**) y V** (Estimation of staff lens doses during interventional procedures. Comparing cardiology, neuroradiology and interventional radiology) se han recopilado las dosis a los profesionales medidas con dosímetros electrónicos llevados sobre el delantal (sin protección) para estimar las dosis en cristalino en varias especialidades intervencionistas. En el **trabajo**

IV (Occupational eye lens doses in interventional cardiology. A multicentric study) se han medido en salas de cardiología intervencionista de 5 centros distribuidos por todo el territorio nacional, obteniéndose registros en 699 procedimientos. Se ha medido una dosis promedio en solapa sobre el delantal de 46 μSv/procedimiento en el cardiólogo más expuesto, siendo muy diferente entre los distintos centros 23-66 μSv/procedimiento. Estos valores están en el mismo orden de magnitud que los publicados en un estudio europeo por el grupo ORAMED de 50 μSv/procedimiento [58]. Una extrapolación anual, suponiendo una carga de trabajo de 50 procedimientos al mes, supondría una dosis sobre el delantal de 25 mSv/año. Se ha registrado una dosis máxima sobre el delantal de 1200 μSv en un único procedimiento, que puede tomarse como indicativo del nivel de riesgo en este tipo de salas en los casos más desfavorables. También se encontraron importantes diferencias en las dosis ocupacionales con la complejidad de los procedimientos. Mientras que para las angiografías coronarias o las angioplastias de complejidad normal las dosis promedio resultaron por debajo de 50 μSv/procedimiento, en el caso de procedimientos más complejos como las angioplastias con oclusiones totales crónicas, o los procedimientos de cardiología estructural tuvieron dosis ocupacionales promedio en solapa sobre el delantal por encima de los 100 μSv/procedimiento.

En uno de los centros se ha medido la dosis en la parte exterior de las gafas de protección con dosímetros OSL en 120 procedimientos, encontrándose una de correlación moderada (r^2 = 0,6) entre la dosis en solapa sobre el delantal y la dosis en gafas, indicando que es posible estimar, aunque de un modo conservador, la dosis en cristalino como el 80% de la lectura sobre el delantal en caso de no llevar gafas de protección. Esto coincide con estimaciones realizadas por otros autores [82-83]. Otros estudios basados en medidas con

maniquí [81], han encontrado importantes diferencias entre la dosis en solapa y la dosis en cristalino debido a múltiples factores físicos y geométricos (calidad del haz, angulación de brazo etc.) que intervienen en esas estimaciones.

El dosímetro colocado en el arco es indicativo del nivel de radiación dispersa en los casos más desfavorables cuando no se usa protección. En este estudio, en la muestra de 699 casos de cardiología intervencionista, se ha obtenido un valor promedio en el arco de 700 μSv por procedimiento.

En el **trabajo V** (Estimation of staff lens doses during interventional procedures. Comparing cardiology, neuroradiology and interventional radiology) se comparan las dosis ocupacionales $H_p(10)$ medidas en solapa sobre el delantal con dosimetría electrónica en tiempo real, para estimar dosis en cristalino en distintas disciplinas intervencionistas, la cardiología, la radiología y la neurorradiología intervencionistas. En 698 procedimientos se han registrado dosis mediana/promedio medidas sobre el delantal del facultativo más expuesto por procedimiento de 21/65 μSv en cardiología, 19/46 μSv en neurorradiología y de 24/57 μSv en radiología intervencionista. La forma de las distribuciones resultó ser muy asimétrica, con valores máximos mucho mayores que el promedio. Los valores de la mediana y promedio para la radiación dispersa medidas en el arco por procedimiento, resultaron ser 682/982 μSv para cardiología, 646/1103 μSv para neurorradiología y 449/764 para radiología intervencionista. El nivel de radiación dispersa medida en el arco del equipo de rayos-X nos informa del nivel de riesgo en estas salas donde se realizan este tipo de procedimientos. Por ejemplo, durante el año 2015, en las salas de cardiología se realizaron un promedio de 57 procedimientos por mes y sala, por lo tanto, se habrían acumulado a lo largo del año 0,7 Sv de radiación dispersa en promedio en el punto del arco que se toma como referencia. En las salas de neurorradiología y radiología intervencionista, se habrían acumulado durante un

año y en el punto de referencia del arco, 0,4 y 0,8 Sv respectivamente. Los facultativos, dado que además del delantal plomado, usaron medidas adicionales de protección, que en unos casos fue el uso de la mampara (cardiólogos y neurorradiólogos intervencionistas) y en otro caso fue el adquirir las series de sustracción digital desde la sala de control (radiólogos), registraron dosis mucho menores que en el arco. Considerando un promedio de 50 procedimientos al mes, las dosis acumuladas en solapa durante un año ascenderían a 36 mSv en cardiología, 25 mSv en neurorradiología y 31 mSv en radiología intervencionista, indicando un nivel de riesgo importante que puede ser reducido considerablemente con un mejor uso de la mampara suspendida del techo o en el caso del cristalino, con el uso de gafas de protección. Las diferencias entre las medianas y los valores medios indican una distribución de frecuencias muy asimétrica con algunos valores altos de dosis. De hecho, los valores máximos por procedimiento registrados en solapa fueron de 995, 558 y 726 μSv para cardiología, neurorradiología y radiología intervencionista respectivamente, siendo indicativo de que puede optimizarse el uso de la mampara plomada para reducir las dosis.

El valor medio del cociente de la dosis medida en la solapa entre la dosis al paciente fueron 0,36 $\mu Sv/(Gy \cdot cm^2)$ para cardiología, 0,21 $\mu Sv/(Gy \cdot cm^2)$ para neurorradiología y 0,46 $\mu Sv/(Gy \cdot cm^2)$ para radiología intervencionista. La diferencia entre el caso de neurorradiología 0,21 $\mu Sv/(Gy \cdot cm^2)$ y la radiología intervencionista 0,46 $\mu Sv/(Gy \cdot cm^2)$ puede deberse a que los radiólogos intervencionistas no usaron apenas la mampara plomada suspendida del techo, siendo la medida de protección más utilizada la de salir de la sala de exploraciones durante la adquisición de las series de sustracción digital (usando inyector automático de contraste), mientras que en la sala de

neurorradiología, además de abandonar la sala durante las series de sustracción digital, también usaron regularmente la mampara suspendida del techo.

6. CONCLUSIONES

1. Las dosis que reciben los pacientes en el cerebro durante los procedimientos terapéuticos de neurorradiología intervencionista son susceptibles de superar el umbral de dosis en cerebro de 0,5 Gy establecido por ICRP. Durante las embolizaciones cerebrales un 40% de los casos analizados superaron este umbral, llegándose a impartir hasta 1,7 Gy en cerebro. Este hecho debe ser tenido en cuenta en la justificación de los procedimientos. Es necesario prestar especial atención a la optimización de los procedimientos, en particular hacer un uso adecuado de la colimación del haz de radiación, especialmente en pacientes jóvenes y niños.
2. Durante los procedimientos terapéuticos en neurorradiología intervencionista, las dosis que reciben los pacientes en el cristalino más cercano al foco del arco lateral (en sistemas de rayos-X biplanos), tiene alta probabilidad de recibir dosis por encima del umbral de 0,5 Gy establecido por ICRP. Un 16% de los casos terapéuticos analizados en este estudio superó dicho umbral, con dosis máximas en el cristalino izquierdo de 2 Gy. La repetición de procedimientos, que suele ser frecuente en patologías complejas, pueden llevar a administrar dosis altas en el cristalino que podrían producir cataratas. Los facultativos deben tener en cuenta estos riesgos en los consentimientos informados, así como aconsejar adecuadamente a los pacientes y sugerir el seguimiento de posibles lesiones cuando sea procedente.
3. En la muestra analizada de casos de cardiología intervencionista (diagnósticos y terapéuticos), un 1% superaron el umbral de 2 Gy de dosis pico en la piel. El sistema de estimación de dosis en piel en tiempo real informa con precisión suficiente de la dosis pico a los

cardiólogos intervencionistas para que, en los casos en los que acumulen más de 2 Gy en la piel, puedan cambiar las proyecciones para evitar posibles lesiones en piel. Sería deseable extender este tipo sistemas que muestran el mapa de dosis en la piel en tiempo real a otras disciplinas intervencionistas.

4. Para cargas de trabajo entre 40 y 60 procedimientos al mes, una extrapolación anual de la dosis ocupacional promedio medida sobre el delantal (46 μSv) resulta en dosis anuales entre 20 y 25 mSv. Por lo tanto, los profesionales de las disciplinas intervencionistas pueden superar el nuevo límite de dosis para cristalino de 20 mSv/año recomendado por ICRP si no se protegen adecuadamente. Puede ser necesaria la monitorización de la dosis en cristalino para estos profesionales dependiendo de su carga de trabajo y de la complejidad de los procedimientos. El uso regular de la mampara suspendida del techo y las gafas de protección reducen sustancialmente las dosis a niveles por debajo de este límite.
5. El abordaje de patologías más complejas, como la cardiología estructural o las angioplastias con oclusión total crónica, casos en los que se ha medido dosis ocupacionales promedio sobre el delantal de 100 μSv/procedimiento (el doble que en otros procedimientos menos complejos), suponen un aumento del riesgo radiológico ocupacional de los profesionales que requiere la continua vigilancia de las dosis en las salas de intervencionismo.

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ARTÍCULOS CIENTÍFICOS RELACIONADOS CON LA MATERIA

8.1 TRABAJO I

Dosis de radiación en cerebro en una sala de neurorradiología intervencionista.

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ORIGINAL RESEARCH
PATIENT SAFETY

Brain Radiation Doses to Patients in an Interventional Neuroradiology Laboratory

R.M. Sanchez, E. Vano, J.M. Fernández, M. Moreu, and L. Lopez-Ibor

ABSTRACT

BACKGROUND AND PURPOSE: In 2011, the International Commission on Radiologic Protection established an absorbed-dose threshold to the brain of 0.5 Gy as likely to produce cerebrovascular disease. In this paper, the authors investigated the brain doses delivered to patients during clinical neuroradiology procedures in a university hospital.

MATERIALS AND METHODS: The radiation dose delivered to the brain was investigated in 99 diagnostic and therapeutic interventional neuroradiology procedures. Brain doses were calculated in a mathematic model of an adult standard anthropomorphic phantom by using the technical and radiation dose data of an x-ray biplane system submitted to regular quality controls and calibration programs.

RESULTS: For cerebral embolizations, brain doses resulted in a maximum value of 1.7 Gy, with an average value of 500 mGy. Median and third quartile resulted in 400 and 856 mGy, respectively. For cerebral angiography, the average dose in the brain was 100 mGy.

CONCLUSIONS: This work supports the International Commission on Radiologic Protection recommendation on enhancing optimization when doses to the brain could be higher than 0.5 Gy. Radiation doses should be recorded for all patients and kept as low as reasonably achievable. For pediatric patients and young adults, an individual evaluation of brain doses could be appropriate.

ABBREVIATIONS: AK = air kerma; CBCT = conebeam CT; DAP = dose-area product; ICRP = International Commission on Radiologic Protection; INR = interventional neuroradiology

Interventional neuroradiology (INR) provides important benefits to public health, but the use of ionizing radiation has inherent risks that must be evaluated and minimized. The new technology available has the potential to manage radiation risks properly but also allows more complex procedures to be undertaken that may require higher radiation doses for patients and staff. For instance, the inclusion of conebeam CT (CBCT) in modern INR laboratories offers advantages to patients in clinics but may also contribute to increased radiation doses.[1,2] The brain had traditionally been considered a highly radioresistant organ, but Shimizu et al[3] have recently reported a 9% excess relative risk per Gray for stroke death with brain doses above 0.5 Gy. The International Commission on Radiologic Protection (ICRP) has reviewed recent epidemiologic evidence suggesting that there are some tissue-reaction (deterministic) effects, particularly those with very late manifestation, in which threshold doses are or might be lower than previously considered. Although uncertainty remains, medical practitioners should be made aware that the absorbed-dose threshold for circulatory disease may be as low as 0.5 Gy to the brain.[4] Doses of such magnitude to patients could be reached during some complex interventional procedures; therefore, particular emphasis should be placed on optimization in these circumstances. The ICRP has also stated that in the case of pediatric patients, low-dose irradiation (1–2 Gy) to the developing brain of children can cause long-term cognitive and behavioral defects, and infants treated before 18 months[4] of age are even more susceptible to cognitive impairment in adult life after exposures to doses of >0.1 Gy.

Therefore, although these procedures have clear net clinical benefits for patients, it is necessary to know the range of radiation doses delivered to help INR specialists manage radiation risks so that they can provide appropriate information and counseling to their patients. There are few research articles on the topic of patient doses in INR, and the existing articles focus most often on the dose to the skin, the effective dose, or other dose indicators,[5–10] but they rarely deal with brain doses.

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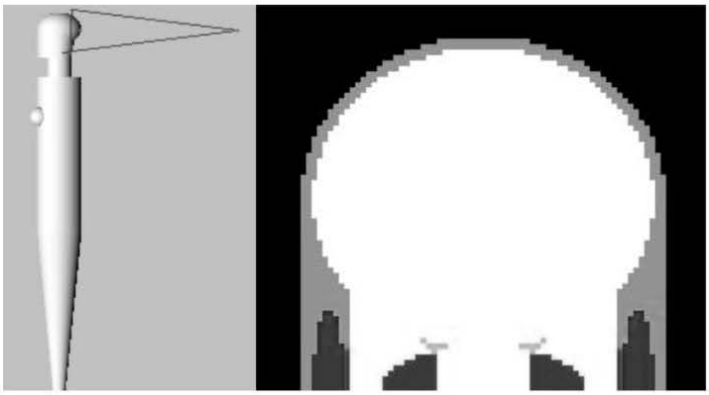

FIG 1. Anthropomorphic phantom used for brain-dose calculation. On the left, a posterior beam projection on the phantom head is shown. On the right, details of the phantom cranium and brain.

Regulations in some countries of the European Union require recording the radiation dose delivered to patients who undergo interventional procedures. In the new Council Directive on protection against ionizing radiation,[11] the European Commission has stated that "information relating to patient exposure forms part of the report of the medical radiological procedure." Modern INR units do not currently provide radiation doses delivered to patient organs. Instead, they can supply patient dose indicators like kerma area product, also used as dose-area product (DAP),[12] and air kerma (AK) at the patient entrance reference point,[13] provided they are suitably validated by a specialist. Because these dose indicators are not generally related directly to patient organ doses, which are the dosimetric quantities relevant to evaluate the biologic effects, the estimation of such doses requires individual calculation by a medical physicist.

In this work, brain doses delivered during INR procedures are reported for a sample of patients at a university hospital. The calculation was performed by using a mathematic model of an anthropomorphic phantom and detailed irradiation parameters recorded from clinical procedures (ie, all fluoroscopy runs and acquisition series). The influence of other variables in brain doses such as the DAP, AK, and beam collimation were also analyzed.

MATERIALS AND METHODS

Cases of diagnostic cerebral angiography and intracranial embolization were recorded sequentially during a 3-month period. Interventions at carotid and cervical levels were excluded. All procedures were performed in a neuroradiology room equipped with an Allura FD 10/20 (Philips Healthcare, Best, the Netherlands) biplane x-ray unit. The frontal C-arm has a flat detector with a 48-cm diagonal, and the lateral C-arm has a flat detector with a 25-cm diagonal. When locating the patient's head at isocenter, with the image detectors 10 cm from the patient's head and with no collimation, the frontal detector covers approximately 27×27 cm^2 and the lateral detector, 14×14 cm^2. Both C-arms have transmission ionization chambers installed at the x-ray tube exit to monitor the DAP delivered to patients, which is included in the patient dose reports. In most procedures, digital subtraction angiography series are acquired at 2 images per second during the first 10 seconds and at 1 image per second during the rest of the time. The system has the ability to perform 2 types of CT volumetric image acquisitions (conebeam CT) depending on the CT mode selected, either 313 images (low-dose CT mode) or 622 images (high-dose CT) over a 240° arc rotation with the largest possible beam size. Whatever the CT mode, the system always works with the same technique: 120 kV, 250 mA, 5 ms, and 0.4-mm Cu +2 mm Al of added filtration. At the end of all therapeutic procedures at our center, at least 1 CT series, approximately equivalent (in DAP) to 2.7 DSA series or 38 DSA images (cerebral protocol at our center), was acquired in the high-dose mode. For some procedures, a 3D reconstruction series obtained with rotational acquisition was performed.

The program PCXMC 2.0 Rotation (http://www.stuk.fi/sateilyn-hyodyntaminen/ohjelmat/PCXMC/en_GB/pcxmc/)[14] was used to calculate brain doses. This program calculates organ-equivalent doses and effective dose in a mathematic model of an anthropomorphic phantom of different ages and sizes. The program performs Monte Carlo simulations throughout the anthropomorphic phantom by using patient dose indicators (DAP, incident air kerma, and so forth) and geometric and physical parameters of the different x-ray projections (kilovolt, added filtration, C-arm angulation, and so forth). All calculations were performed on the standard phantom (Fig 1) corresponding to an adult measuring 179 cm and weighing 73 kg and containing the anatomic data based on the mathematic model of Cristy and Eckerman.[15]

Detailed information of the geometric and physical parameters was recorded for each beam projection at series level on the x-ray system and extracted with the help of Philips support engineers. This information, now directly available from the DICOM Radiation Dose Structured Reports, provided the x-ray system has been upgraded to allow this functionality, includes generator and x-ray tube setting potential (kilovolt), tube current (milliampere), pulse duration (milliseconds), added filtration, beam collimation, and C-arm angulations per projection for all fluoroscopy runs and DSA acquisition series. DAP and AK were also provided for each projection, then verified and corrected by a medical physicist, taking into account the couch and mattress attenuation in the frontal C-arm and the calibration of the DAP meter.

For the calculation of brain doses, DAP was used. The Philips Allura FD 20/10 has distances from the focus to rotation axis of 81 and 76.5 cm for the frontal and lateral C-arms, respectively. All data used to calculate patient doses were obtained from the data recorded at the radiation unit during clinical procedures, with the exception of the positioning of the patient whose brain is to be centered at the C-arm isocenter (a precondition of the conebeam CT acquisitions). The x-ray beam characteristics were introduced in the software by using the kilovolt and added filtration used on each beam projection. A fixed inherent filtration of 2.5 mm Al and anodic angles of 11° and 9° for the frontal and lateral x-ray tubes,

respectively, were also used. Wedge compensation filters were not used in our center for these procedures.

The brain doses calculated were compared with patient dose indicators (DAP and AK) and beam collimation.

RESULTS

Of 99 procedures recorded, 61 were cerebral angiographies and 38 were cerebral embolizations. On average, the diagnostic cases have lower DAP (64.5 Gy · cm^2) than the therapeutic ones (230 Gy · cm^2). The average number of projections (fluoroscopy runs and DSA acquisitions) was 49 for cerebral angiographies and 159 for therapeutics. A total of 9031 beam projections were processed for the brain-dose calculations. The main statistical parameters for brain doses are presented in Table 1. Figure 2 shows the frequency histograms. Thirty-four percent of therapeutic procedures had brain doses of ≥500 mGy. The total number of procedures (n = 99) corresponds to 81 patients because 14 patients underwent >1 procedure in the 3 months. If one takes into account the repetition of procedures, of the 38 patients with at least 1 therapeutic procedure, the fraction of patients with brain doses of >500 mGy is 40%, and with doses of >1000 mGy, 19%. Ten of 15 patients with brain doses greater than 500 mGy underwent >1 procedure.

Table 1: Main statistics for brain doses (in mGy) for cerebral angiography and embolization

	Cerebral Angiography	Cerebral Embolization
No.	61	38
Minimum	26	155
Maximum	568	1678
Mean	100	500
SD	92	346
1st Quartile	45	250
Median	73	397
3rd Quartile	123	645

Figure 3 presents brain doses versus DAP and AK. Lines show Pearson correlation coefficients of >0.9 for both variables. Figure 4 shows the brain dose relative to the AK ratio represented versus the weighted average field size for each procedure. The average field size for each patient is weighted by the DAP of each projection. An average difference of a factor of 2 can be observed in brain doses between the greatest and smallest field sizes.

The dose delivered during a CBCT series was 23.5 Gy · cm^2 in terms of DAP for the high-dose CBCT, which yielded a calculated 32 mGy to the brain and 1.65 mSv of effective dose (ICRP-103).[16] In the case of the low-dose CBCT, which uses half the projections with the same settings, brain and effective doses were also halved.

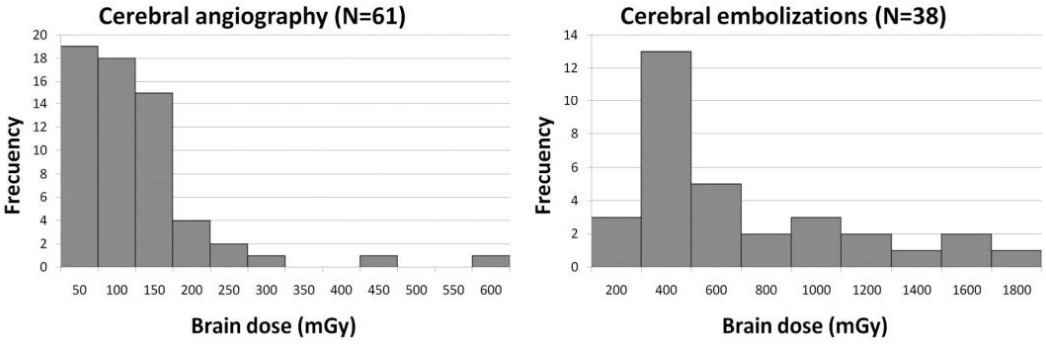

FIG 2. Frequency histogram with brain doses for cerebral angiography and embolization. Average brain dose resulted in 100 mGy for cerebral angiography and 500 mGy for embolizations.

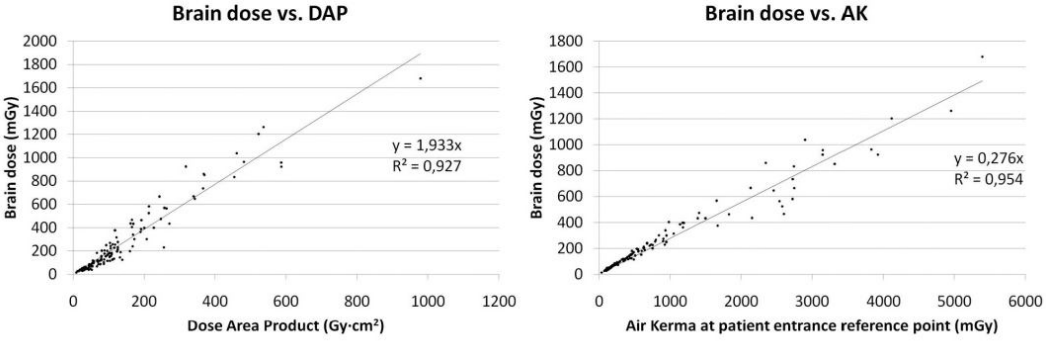

FIG 3. The brain dose for the 99 procedures is represented versus the 2 main dose indicators provided by modern interventional x-ray units, DAP and AK. Linear regression presents good correlation.

DISCUSSION

Doses as high as 1.7 Gy have been delivered to the brain during a therapeutic procedure in the sample of procedures included in this work. In 34% of these procedures in our institution, the dose exceeded 500 mGy (ie, the new dose threshold set by the ICRP). Given that, in some cases, several procedures are performed on the same patient, 40% of the patients in the sample investigated received >500 mGy in the brain. In diagnostic procedures, exceeding this threshold dose is unlikely. The ICRP has fixed the dose threshold when the probability of radiation injury is >1%. In the case of death from stroke, the excess of relative risk reported by Shimizu et al[3] is 3% between 0 and 0.5 Gy and approximately 11% for 1.5 Gy. Most of these therapeutic procedures are clearly justified for clinical reasons (they are life-saving), more particularly when they are expected to prevent stroke death, but the radiation doses to the brain reported in this article show that optimization, as recommended by the ICRP, is essential, especially in young patients with long life expectancies after interventions.

Figure 5 shows age histograms for the sample of patients investigated. Values for mean, median, and first quartile are quite similar for angiographies and embolizations. The average age of patients was 56 years, with a median of 60 years and a 25th percentile of 47 years; in both types of procedures, there was 1 patient younger than 15 years. Therefore, in such procedures, radiation risks must be taken into account, especially with pediatric patients and young adults.

When we compared scientific articles already published, we found that most publications reported patient dose indicators like DAP, AK, or skin dose. Miller et al[5] reported DAP in a multicenter survey in the United States, with an average DAP of 320 Gy · cm^2 for embolizations, 39% higher than in this work (230 Gy · cm^2). Sandborg et al[8] investigated skin doses to the head during INR cases and reported an average DAP for embolization of 189 Gy · cm^2. Thierry-Chef et al[7] investigated brain doses in a sample of 49 pediatric patients undergoing intracranial embolizations. Depending on the beam collimation (not reported in the article), the average brain dose could range from 68 to 490 mGy for the high and low levels of collimation, respectively. In this survey, mainly focused on adult patients, the average brain dose was 500 mGy.

A good correlation was shown between DAP and AK in the sample investigated, probably because of the simple irradiation geometry of the cranial procedures and the level of collimation. These findings make it possible to estimate brain doses with reasonable accuracy if the dose indicators (DAP and KA), available in most modern interventional x-ray units, are properly calibrated. The variability found in the literature on DAP values and brain doses indicates that a diligent mode of operation is essential to optimize radiation doses. Figure 3 shows that if one uses a beam size as small as possible, important dose reductions can be achieved and that when one uses x-ray beams with high filtration, brain doses can be reduced drastically during fluoroscopy runs and DSA acquisitions.

The dose delivered to the brain during a high-dose CBCT resulted in 32 mGy, 32% of the mean brain dose for a diagnostic procedure. In embolizations, with a higher mean dose (500 mGy), 1 high-dose CBCT represented 6% of the total brain dose. Other studies[17,18] have reported lower values of CBCT doses in the head as shown in Table 2. These lower values are mainly consequences of the use of automated exposure controls to adjust the dose required to a minimum for each projection and, in some cases, of a lower number of projections. However, the ratio effective dose over the DAP is of the same order of magnitude (Table 2). Koyama et al,[19] who measured doses in a phantom with a protocol but without automated exposure control and similar kilovolt and milliampere-second settings, reported brain doses similar to those in this study.

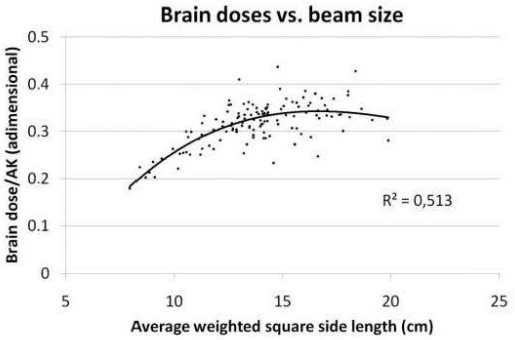

FIG 4. For the 99 procedures, the brain dose is related to the average weighted field size. In both images, one can appreciate how brain doses are almost doubled when the field size rises from 8 to 15 cm or more.

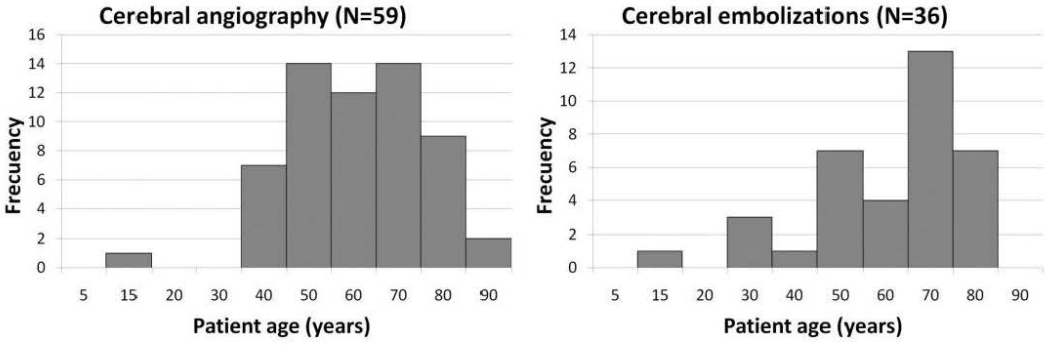

FIG 5. Age histograms for the sample of patients in this survey.

Table 2: Comparison of dose parameters in CBCT with other authors[a]

	DAP ($Gy \cdot cm^2$)	Brain Equivalent Dose (mGy)	ED ICRP-103[16] (mSv)	ED/DAP ($mSv/[Gy \cdot cm^2]$)
Koyama et al (2010)[19]	—	14–37	0.47–1.2	—
Kim et al (2012)[17]	5.99–9.61	5–6	0.38–0.87	0.06–0.09
Bai et al (2013)[18]	9.4 ± 2	6	0.30 ± 0.08	0.03–0.035
This study	11.75–23.5	16–32	0.83–1.6	0.09

Note:—ED indicates effective dose estimated with the parameters from the document ICRP-103.

[a] Kim et al and Koyama et al provide a range of dose estimations for several situations (kilovolt, collimation, or gantry tilt). Bai et al provide mean values ± SD for a sample of patients, except for the brain dose, for which they provide a phantom estimation.

The approach and process for calculating brain doses have some limitations. It was assumed that all fluoroscopic series were delivered to the brain, when, in fact, most procedures start at the femoral artery and a small part of the initial fluoroscopy could be made in the abdomen. Another source of inaccuracies could result from taking for granted that the patient brain is always centered at the C-arm isocenter, which happens not to be the case in some parts of the procedure. Therefore, in some cases with a large fluoroscopy time at leg or aortic levels and in cases in which the lesion is located at the brain peripheral region, a small overestimation of brain doses may be observed. Our approach could, therefore, be considered as a conservative estimation of brain doses in INR procedures.

CONCLUSIONS

The dose delivered to the brain of patients undergoing interventional neuroradiology procedures may be relevant enough to produce radiation side effects and must be minimized as much as possible. The radiation dose to patients should be monitored for all interventional procedures by using the standardized dose indicators DAP and AK and should be included in the patient clinical report. For interventions of high complexity and high radiation doses, an individual dose calculation to some sensitive organs/tissues like the brain, eye lenses, or skin may be needed, especially for pediatric patients and young adults and patients likely to undergo repeat procedures. To optimize the procedures and minimize patient doses, one must reduce the number of series, the number of frames per series, and the frame rates to the minimum necessary; collimate the radiation beam to the region of interest; reduce the detector-to-patient distance; and use x-ray beams with high-added filtration. It is also important to have a quality-assurance program to ensure that the x-ray dose rate remains within acceptable values.

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8.2 TRABAJO II

Dosis de radiación en cristalino de pacientes durante procedimientos de neurorradiología intervencionista

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ORIGINAL RESEARCH
PATIENT SAFETY

Radiation Doses in Patient Eye Lenses during Interventional Neuroradiology Procedures

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ABSTRACT

BACKGROUND AND PURPOSE: Eye lenses are among the most sensitive organs to x-ray radiation and may be considered at risk during neurointerventional radiology procedures. The threshold dose to produce eye lens opacities has been recently reduced to 500 mGy by the International Commission on Radiologic Protection. In this article, the authors investigated the radiation doses delivered to patients' eyes during interventional neuroradiology procedures at a university hospital.

MATERIALS AND METHODS: Small optically stimulated luminescence dosimeters were located over patients' eyes during 5 diagnostic and 31 therapeutic procedures performed in a biplane x-ray system. Phantom measurements were also made to determine the level of radiation to the eye during imaging runs with conebeam CT.

RESULTS: The left eye (located toward the lateral C-arm x-ray source) received a 4.5 times greater dose than the right one. The average dose during embolization in the left eye was 300 mGy, with a maximum of 2000 mGy in a single procedure. The patient who received this maximum eye dose needed 6 embolization procedures to treat his high-volume AVM. If one took into account those 6 embolizations, the eye dose could be 2-fold. Sixteen percent of the embolizations resulted in eye doses of >500 mGy.

CONCLUSIONS: A relevant fraction of patients received eye doses exceeding the threshold of 500 mGy. A careful optimization of the procedures and follow-up of these patients to evaluate potential lens opacities should be considered.

ABBREVIATIONS: CBCT = conebeam CT; DAP = dose-area product; ICRP = International Commission on Radiological Protection; INR = interventional neuroradiology; OSLD = optically stimulated luminescence dosimeter

Interventional neuroradiology (INR) activity has increased in recent years, providing important benefits to patients, but the use of ionizing radiation adds risks that must be evaluated and minimized. Concerning eye lens irradiation during INR procedures particularly, little research has been conducted, yet it is important for physicians to know the level of risk for this organ in these kinds of procedures. The International Commission on Radiological Protection (ICRP) has recently published a report on the effects of radiation in tissues and organs, in which it recognizes that eye lenses may be more sensitive to ionizing radiation than previously thought.[1] Until recently, the dose threshold suggested for the formation of lens opacities was 5 Gy in case of acute irradiation of the eye lens.[2] However, as a result of new epidemiologic evidence,[3,4] this threshold value has been reduced to 0.5 Gy,[1] the legislation on radiation protection of workers has been amended, and the dose limits for the lens of the eye reduced in the International Basic Safety Standards[5] and in the new European regulation.[6] In the case of patients, to optimize procedures and reduce radiation doses, the new European legislation[6] requires that the information relative to patient exposure be included in the medical report. In addition, radiation doses averaged from patient samples have to be compared with national diagnostic reference levels, and if relevant deviations are detected, optimization actions should be taken. As in the case of the authors' country, there may be no formal national diagnostic reference levels available. In such a case, other regional or local diagnostic reference levels could be used until the national diagnostic reference levels are established.

There is little information in the literature regarding the eye lens dose received by patients during INR procedures. Moritake et al[7] reported average doses in patients' eyes of 380 mGy, with a maximum of 2079 mGy during cerebral embolizations, 4 times the threshold level of 500 mGy recommended by the ICRP. Sandborg et al[8] reported mean and maximum doses in the eye of 71

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and 515 mSv, respectively, also during cerebral embolizations. The variability of doses found then underlines the need for further investigations into the risks associated with these medical practices. Practitioners also need to know the order of magnitude of the radiation doses delivered to patients' eyes during INR procedures. These data will allow physicians to optimize radiation protection during clinical procedures, to better manage the information about the risks of radiation-induced lens opacities, and to give patients the appropriate counseling on the follow-up.

This article presents the measurement of patient eye lens doses, by using optically stimulated luminescence dosimeters (OSLDs). Eye doses were measured in a sample of diagnostic and therapeutic procedures performed in an interventional neuroradiology laboratory at a university hospital. The contribution of conebeam CT (CBCT) to eye lens doses was also investigated.

FIG 1. Position of the dosimeters on patient eyes.

MATERIALS AND METHODS

Cases of cerebral angiography ($n = 5$) and therapeutic ($n = 31$) procedures were randomly selected for this study. The therapeutic procedures consisted of embolizations of AVMs ($n = 13$) mainly with grades IV and V (Spetzler-Martin[9]); fistulas ($n = 2$); and aneurysm coiling ($n = 16$). All procedures were performed in the neuroradiology room equipped with an Allura FD 10/20 (Philips Healthcare, Best, the Netherlands) biplane x-ray unit at the Hospital Clinico San Carlos in Madrid, Spain. The diagonals of the flat detectors were 40 cm for the frontal C-arm and 25 cm for the lateral one. The lateral C-arm has its x-ray focus at the patient's left side (supine). When the patient's head is located at isocenter with the image detectors 10 cm from the patient's head and no collimation, the frontal detector covers the patient's surface area of approximately 27×27 cm^2, and the lateral detector, 14×14 cm^2. Both C-arms have transmission ionization chambers installed at the x-ray tube exit to monitor the radiation dose delivered to patients; the dose is included in the patient's dose reports. In most procedures, the digital subtraction angiography series was obtained at 2 images per second in the first 10 seconds and at 1 image per second in the remaining time.

The system, by using the conebeam CT technique, has the ability to acquire volumetric images. Depending on the CBCT mode selected, low dose or high resolution, 313 or 622 images can be acquired over a 240° arc rotation for volumetric reconstruction. The CBCT is performed by rotating the arc around the posterior side of the patient (in a supine position), with a rotation angle from −120° to 120°, minimizing irradiation to the patient's face. During CBCT acquisitions, the generator settings are as follows: 120 kV, 250 mA, 5 ms, 0.4-mm copper (Cu) +1-mm aluminum (Al) of added filtration. The maximum field size of 27×27 cm^2 is set at the isocenter. At least 1 CBCT series was acquired during the therapeutic procedures. The x-ray system was submitted to regular quality control and calibration programs by the medical physics service, as recommended by the national guidelines. The neuroradiologists in charge have received training in radiation protection as required by national regulation.

The radiation dose at the eye lens was estimated by measuring the entrance surface air kerma with small OSLDs. For simplicity, from now on, the word "dose" will refer to the entrance surface air kerma at the eye lens. For each patient, 2 OSLDs were located over the eyelids as shown in Fig 1. The OSLDs used were the nanoDot model (Landauer, Glenwood, Illinois). They are composed of a small disk of 4-mm diameter of optically stimulated luminescent material (Al_2O_3:C), which forms the active area, encased in a light-tight plastic protector of $10 \times 10 \times 2$ mm^3. Their small size makes them suitable for use near patients' eyes. OSLDs have been previously used to measure patient doses in different clinical situations,[10-12] but when used with diagnostic energies, special attention must be paid to limitations such as energy and angular dependence.

In neuroradiology procedures, the x-ray beam quality may change with kilovolt settings and filtration. Kilovolt settings are adjusted by automatic dose control of the flat detector, depending on patient thickness. For the neuroradiology protocols programmed in Allura, the beam kilovolt is nearly constant around 70–80 kV. However, filtration may change depending on the operation mode selected by the user and may range from 0.1 mm of copper plus 1 mm of aluminum with the digital subtraction angiography mode to 0.9 mm of Cu plus 1 mm of Al with the fluoroscopic low-dose mode. The OSLDs have been calibrated "in house" by using typical clinical beam qualities from our interventional x-ray unit and verified by the Centro Nacional de Dosimetría in Valencia, Spain, a standard calibration laboratory. With these user x-ray beams, a difference of 6% in the calibration factor for 70 and 80 kV was observed for the same filtration, while a difference of 16% was measured for different filtrations. The uncertainty resulting from the response of OSLDs to kilovolt variation (6%) was assumed acceptable, but the effect of different filtration in the OSLD response had to be corrected. To reduce the influence of the different added filtration of the x-ray beams in the OSLD response, we used the information included in the patient dose report about the air kerma area product.[13]

The air kerma area product, commonly called dose-area product (DAP), is one of the standard magnitudes used to monitor patient doses in some x-ray modalities. Modern interventional x-ray equipment provides the DAP in both DICOM

headers and patient dose reports and can be used as a patient dose indicator, provided it is duly calibrated. In this case, the DAP meter had a deviation of −10%, and all DAP values had been duly corrected. Our x-ray unit produces patient dose reports that provide the fraction of the DAP delivered with fluoroscopy (high added filtration) and with DSA (low added filtration). This information was used to calculate a corrected calibration factor for each procedure, by combining the calibration factors for fluoroscopic and DSA beams proportionally to the fraction of fluoroscopic and DSA DAP included in the dosimetric report. Once the calibration factor had been derived for each procedure, the OSLD reading was then translated into dose. Regarding angular dependence and for the beam qualities used in this study, angular dependence has been measured and resulted in a difference in response of −15% in the worst case (beam incidence of −90° in the lower energetic beam) and −3% for high-filtered beams. Besides the eye dose, other relevant parameters were recorded, such as the dose at the patient entrance reference point,[14] the fluoroscopy time, the number of DSA and CBCT series, and the number of images.

FIG 2. Anthropomorphic phantom with OSLDs over the eyes.

To measure the dose contribution to the eyes during CBCT runs, we performed a phantom simulation. We laid down an anthropomorphic phantom model, Rando (The Phantom Laboratory, Salem, New York), over the examining couch, centering the phantom head at the isocenter. Optically stimulated luminescence dosimeters were attached over the phantom eyes (Fig 2). Doses at the phantom eyes were measured with the 2 modes of operation available in this x-ray system: low dose and high resolution. Both modes of operation have been described previously in this section. The specific calibration factor for the CBCT beam quality was measured for the OSLDs.

Regression analysis between the eye dose and DAP was performed with the statistical package SPSS, Version 12 (IBM, Armonk, New York).

An independent local ethics committee approved this study under the title "Radiologic Risks in Fluoroscopy Guided Procedures" (code B-09/20). Patients agreed to allow anonymous dosimetric information to the investigation.

RESULTS

Of 36 procedures measured, 5 were diagnostic and 31 were therapeutic. Table 1 summarizes the main results of patient doses. The maximum doses delivered to the left eye, liable to receive direct radiation from the lateral C-arm, resulted in 81 mGy for diagnostic procedures and 2080 mGy for therapeutic ones. Five of the 31 embolizations (16%) resulted in doses in the left eye greater than the threshold of 500 mGy. Table 2 shows the main dosimetric parameters of those procedures. The linear regression between the DAP (in grays × square

Table 1: Main statistics for parameters related to patient dose for diagnostic and therapeutic procedures

	DAP (Gy × cm²)	Fluoroscopy Time (sec)	No. of DSA Images	Right Eye K (mGy)	Left Eye K (mGy)
Diagnostic (n = 5)					
Min	36	169	87	17	24
Max	86	1581	958	28	81
Mean ± SD	56 ± 21	657 ± 560	484 ± 421	20 ± 11	67 ± 32
Median	44	407	293	23	67
1stQ	44	362	165	21	52
3rdQ	72	768	920	24	77
Therapeutic (n = 31)					
Min	63	680	112	9	32
Max	479	5250	2410	173	2084
Mean ± SD	203 ± 120	1680 ± 900	1030 ± 460	62 ± 37	303 ± 409
Median	164	1400	1000	57	172
1stQ	115	1120	750	42	77
3rdQ	248	2200	1180	76	315

Note:—1stQ indicates first quartile; 3rdQ, third quartile; K, air kerma; Min, minimum; Max, maximum.

Table 2: The dosimetric data for the 5 therapeutic procedures with left eye doses >500 mGy

Procedure	DAP (Gy × cm²)	Fluoroscopy Time (sec)	No. of Images	AK_R Frontal (mGy)	AK_R Lateral (mGy)	Right Eye Dose (mGy)	Left Eye Dose (mGy)
AVM	227	1407	1283	2388	599	–	671
Aneurysm	271	2412	1020	1978	880	58	614
Aneurysm	214	1956	2412	2314	714	118	936
AVM	466	5254	979	3801	1711	129	2080
AVM	423	1801	1801	2220	724	173	911

Note:—AK_R indicates the air kerma in the patient entrance reference point for the frontal and lateral C-arms.

centimeters) and the dose at the left eye (in milligrays) resulted in an expression Dose at Eye = 2.1 × DAP, with a correlation coefficient of $r^2 = 0.63$ ($P < .001$). Figure 3 shows the left and right eye dose histogram for cerebral embolizations.

During a CBCT irradiation, the doses at the patient entrance reference point were 32 and 64 mGy for the low dose and high resolution, respectively. On the anthropomorphic phantom's eyes, the doses were 10 mGy in the CBCT low-dose mode and 20 mGy for the high resolution.

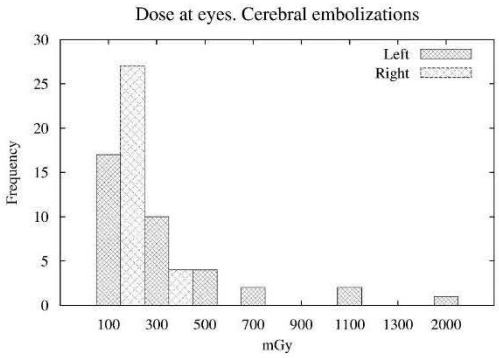

FIG 3. Left and right eye doses measured with OSLDs during cerebral embolizations.

DISCUSSION

The dose values at the phantom's eyes of 10 and 20 mGy measured for this x-ray unit during the CBCT acquisitions correspond to 3%–6% of the average left eye dose for a therapeutic procedure and 15%–30% for a cerebral angiography. Compared with the dose at the patient entrance reference point reported by the x-ray system during a CBCT run, the eye dose resulted in a fraction of 30%. The values in our x-ray system are of the same order of magnitude as the ones reported by Koyama et al,[15] who measured 20 mGy in eye lenses using diodes.

In diagnostic cases, patient DAPs were lower than those in therapeutic cases: 56 ± 21 Gy × cm^2 versus 203 ± 120 Gy × cm^2 (mean ± SD). These values of DAP are even lower than the ones reported by several authors[16-18] who showed average DAPs from 68 to 158 Gy × cm^2 for angiography and from 215 to 382 Gy × cm^2 for embolization. Sandborg et al,[8] who also included eye doses, reported 55 and 190 Gy × cm^2 for angiographies and embolizations, respectively (ie, doses similar to those found in this investigation). The maximum eye dose recorded during a cerebral angiography was 81 mGy, much lower than the threshold of 500 mGy.

The OSLD located at the left eye (in front of the lateral C-arm x-ray tube) read an average dose 4.8 times greater than the one located at the right eye. The average dose of 300 mGy measured at the left eye can be considered important compared with the threshold recommended by ICRP (500 mGy). This mean value is of the same order of magnitude as the one reported by Moritake et al[7] (380 mGy) but much higher than the one reported by Sandborg et al[8] (71 mGy). The sample of Sandborg et al had a mean DAP similar to ours (190 versus 203 Gy × cm^2) for embolizations, but in comparison, the eye doses were drastically lower (71 mGy versus our 300 mGy). In our sample, 5 cases (16%) of the 31 therapeutic procedures measured resulted in doses of >500 mGy at the left eye. With such a level of radiation, the possibility of producing opacities or cataracts in patients' eyes should be considered, especially in patients requiring several procedures to be treated properly. At the right eye, the dose measured was below 200 mGy, a value unlikely to produce opacities.

The maximum radiation dose measured at the left eye was 2080 mGy during an AVM located in the anterior fossa, with a DAP of 466 Gy × cm^2 (88 fluoroscopy minutes and 979 images).

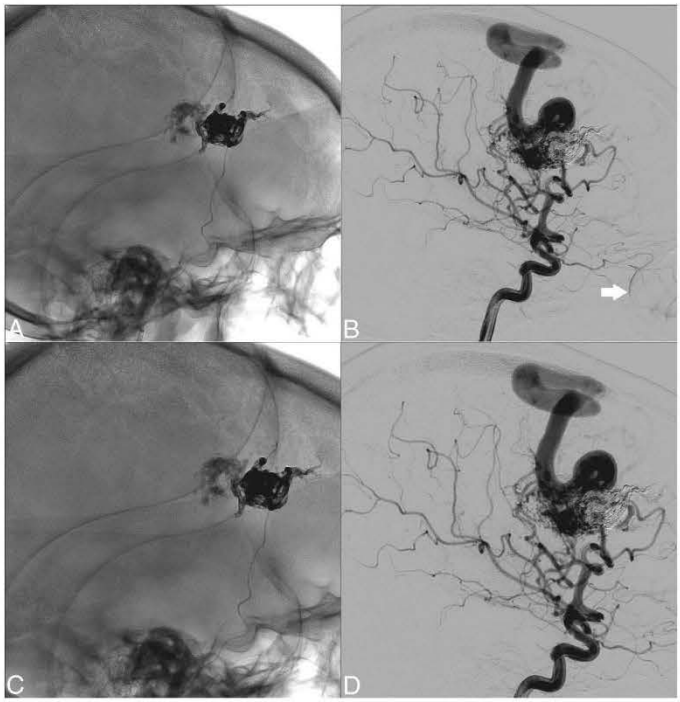

FIG 4. *A* and *B*, Nonoptimal lateral projection without and with subtraction where the left eye is irradiated. *C* and *D*, The proposed collimation to avoid eye irradiation. The *arrow* in *B* indicates some contrast in colloids via the ophthalmic artery that may be chosen as the edge to collimate the lateral beam.

In such a case, opacities in this eye are likely to occur; 4.4 mGy in the left eye per Gy × cm^2 is an extreme case well above the average tendency of 2.1 mGy/(Gy × cm^2). This uncommonly high dose may certainly result from the patient's pathology being located in the anterior fossa, close to the eye. This particular patient, with a high-volume AVM, needed 6 INR procedures within 18 months, with a total cumulative DAP of 800 Gy × cm^2. It was not possible to measure the eye dose with OSLDs in the course of the 6 procedures, but if we assume that no additional measures could be taken to protect the eyes, this patient might have received almost 4000 mGy. This patient and his relatives were informed of the risks of developing cataracts and of how to proceed should this happen.

Another case of interest, with a high DAP of 480 mGy × cm^2 but with a very low eye dose of 94 mGy, was an embolization located at the posterior side of the head, during which the neuroradiologist had taken precautions to protect the patient's eye lenses from the lateral beam in most DSA series. This example shows that even during complex procedures with a large DAP, it is still possible to reduce the eye dose when clinically compatible, provided proper collimation in the lateral beam is used to protect the eye. After further analysis of the sample of procedures, we concluded that in some cases, collimation could be optimized. Figure 4*A*, *-B* shows a nonoptimal lateral projection from an AVM embolization in which the left eye was irradiated. Figure 4*C*, *-D* shows the optimal proposal based on a retrospective analysis during a joint optimization session by neuroradiologists and medical physicists. This collimation provides eye protection while keeping enough FOV to monitor and prevent possible iatrogenic embolizations.

The correlation between DAP, probably the most frequently used dose indicator, and the dose at the left eye was small (r^2 = 0.6), certainly limited by the influence of other factors like the collimation of the lateral beam and the lesion location (close or distant from the eyes). The combination of these 3 variables should, therefore, be taken into account to evaluate the risk of producing lens opacities.

So far the radiation dose has been analyzed during 1 single INR procedure, but it is, however, common for a patient to undergo >1 procedure. This hospital is a reference center for the treatment of AVMs of grades IV and V (Spetzler-Martin): 95% of the AVMs performed here are grades 4 and 5 and all of them require several procedures. In fact, only 6 (17%) of the 36 patients in this sample had undergone only 1 INR procedure at the time; 11 patients (30%) had undergone 3 or 4 procedures; 10 patients (28%), 5 or 6 procedures; and 9 patients (25%), ≥6 procedures. It was not possible to measure the eye doses in all these cases, but all the DAPs were recorded, giving an average of 566 Gy × cm^2, with 17 patients (47%) with >300 Gy × cm^2. This value of 300 Gy × cm^2 is the DAP obtained from the linear regression equation that may produce eye lens doses over the threshold of 500 mGy. The average age of this patient sample was 59 years, with 9 patients (25%) younger than 50 years of age, therefore with a long life expectancy.

Finally, the difference of 10% in calibration factors used for the various procedures indicates that uncertainties due to the response of OSLDs to beam quality have been reduced. Nevertheless and despite the corrections made, other factors arose from the calibration process and the angular dependence of the dosimeters, which could increase the uncertainty to 20%.

CONCLUSIONS

During INR therapeutic procedures in a biplane x-ray system, it is possible to deliver relevant doses to the eye lens. For the sample presented in this article, 16% of the therapeutic procedures measured resulted in eye doses higher than the threshold of 500 mGy for lens opacities. The factors that could modify the eye doses are the DAP delivered, the lesion localization, and the possibility of collimating the lateral x-ray beam to protect the eye. Given that most patients in this sample had undergone several INR procedures, the fraction of patients with a DAP that potentially may result in lens doses over the recommended threshold (>300 Gy × cm^2) was 47%. When optimizing the collimation in the lateral beam to prevent direct eye irradiation, the risk of eye lens opacities is reduced to negligible levels. A follow-up of patients receiving high doses in the eyes should be considered to evaluate potential lens opacities and to decide whether the possibility of producing induced opacities should be included in the informed consent. The most effective actions to minimize eye doses are to collimate to the necessary surgical field, especially in the lateral beam; to avoid unnecessary acquisition series; and to use, when possible, fluoroscopy runs instead of acquisitions.

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8.3 TRABAJO III

Evaluación de un sistema para mostrar el mapa de dosis en piel en procedimientos de cardiología intervencionista

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EVALUATION OF A REAL-TIME DISPLAY FOR SKIN DOSE MAP IN CARDIAC CATHETERISATION PROCEDURES

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The purpose of this work was to validate a prototype designed to display skin dose maps in real time for clinicians that perform interventional cardiology procedures. Measurements using copper absorbers and three kinds of dosemeters (solid-state, radiochromic film and optically stimulated luminescence) were performed in a catheterisation laboratory. Some clinical results are also discussed. The system provides patient skin doses with acceptable accuracy, taking into account couch shifts, wedge compensation filters and collimation. The greatest source of uncertainty is that resulting from patient shape modelling. From a set of 374 patients recorded, it can be concluded that the peak skin dose (PSD) for patients with the same cumulative air kerma at the patient entrance reference point can be rather different. This real-time skin dose calculator has resulted easier to manage for measuring patient PSDs than other methods based on films or CR plates. As well as an improvement for patient safety, it could prove a useful training tool for clinicians.

INTRODUCTION

During interventional cardiology (IC) procedures, patients with different degrees of complex pathologies may occasionally require interventional procedures with large fluoroscopy times or high number of cine series, likely to cause radiation skin injury. Depending on the peak skin dose (PSD) delivered to the patient, some skin injuries could be produced with different degrees of severity from transient erythema (with PSD between 2 and 5 Gy) to more severe reactions including moist desquamation and dermal necrosis (PSD > 15 Gy)[1]. In some cases, skin injuries are unavoidable side effects of life-saving clinical procedures and, in such cases, the knowledge of patient skin dose distribution is needed to provide proper patient counselling or if necessary to programme a clinical follow-up to avoid further complications. In other cases, skin injuries could even be prevented if real-time PSD during procedures and also from past interventions (typically within the last 6–12 months) was available to clinicians. In its recent publication, the new Council Directive on basic safety standards for radiation protection[2] has required that the information relating to patient exposure be included in the report of the medical radiological procedure in the European Union. In IC, the most common radiation quantities recorded by the X-ray units are the kerma area product[3] (KAP) and the incident air kerma (AK) at patient entrance reference point[4], but these indicators are not directly related to the PSD[5]. The International Commission on Radiological Protection has recommended to investigate patients with PSDs of >3 Gy so as to determine whether a follow-up of the possible lesions is needed[6]. In modern IC X-ray systems, AK and KAP are displayed during the procedures in real time, but the reduction of high doses and their optimisation still result difficult in certain regions of the skin. Slow film dosimetry or photo-stimulating image plates were tested[7–10] to measure PSD during fluoroscopic interventional procedures, but they resulted expensive and time-consuming. Some systems based on dedicated software using external computers to offer skin dose maps (SDMs) in real time were proposed in the past[11–14], but they are no longer available. Several radiation protection organisations call for the re-introduction of such tools[6, 15].

In this paper, the authors present the evaluation and validation of a prototype of a real-time display of skin dose distribution designed for IC allowing access to PSD during clinical procedures.

A set of clinical procedures was recorded, and clinical PSD values were analysed.

MATERIALS AND METHODS

The prototype SDM (Philips Medical Systems) was installed in an IC laboratory equipped with a Philips Allura FD10 C-arm. From the X-ray unit, the SDM system recorded all the relevant data such as beam collimation, wedge compensation filters, C-arm and couch position to project the AK on a cylinder surface simulating the patient located over the table. The prototype that was evaluated did not take into account any correction for couch attenuation or

backscatter (BS). The 2D dose distribution projected at a cylinder surface and the maximum AK were shown to the clinicians at the catheterisation laboratory (Figure 1). If skin doses reached 2 Gy, a red-coloured warning was showed in the upper left corner.

The AK was measured by the standard transmission ionisation chamber installed at the X-ray tube exit. This transmission chamber provided the KAP at the catheterisation room at the control panel and transferred this information to the dose report. A Medical Physicist, following national recommendations, validated all these values. The cardiologists could view the resulting dose map displayed in real time inside the catheterisation laboratory with a pixel size of 5 × 5 mm^2 on a separate 10″ screen attached to room monitors. The dose matrix could be exported in xlm format to be analysed.

The validation was performed with copper absorbers positioned on the imaging flat panel detector. A radiochromic film Gafchromic XR RV3 (Ashland) was placed over the couch initially at 61 cm from X-ray focus, i.e. the position of the patient entrance reference point for this C-arm. Additionally, four pairs of optically stimulated luminescence (OSL) dosemeters were attached to the film. OSL and film dosemeters were calibrated with the X-ray beam quality used in this experiment, referenced to a calibrated ionisation chamber Radcal model 20 × 6 (Racal Corp). Over the film, a solid-state dosemeter Unfors Xi (Raysafe) was also positioned to measure incident AK (K_i) without BS. Detectors were irradiated modifying the couch position (laterally and vertically), collimation and the C-arm angulation. The beam quality was also modified by varying the copper thickness—from 4 to 6 mm—placed at the entrance of the image detector. To accumulate enough dose at the radiochromic film (>1 Gy), the high dose rate cine mode without added filtration was used, setting the X-ray tube voltage between 79 and 95 kV. The distance between dosemeters and copper absorbers was long enough to avoid BS. The incident AK measured by those dosemeters was compared with the magnitude provided by the SDM prototype. The software Imagej (http://imagej.nih.gov/ij/index.html) was used to analyse 2D dose distributions.

A set of 374 patients was recorded in the system. The correlation between the AK and the KAP with the maximum AK was also investigated.

RESULTS

The comparison between the SDM reading (without couch attenuation and BS) and the incident AK measured with the solid-state detector (with table attenuation and without BS) showed an average difference of 33 %. 34 % in the case of 79 kV and 32 % when de kV was 91, resulting from couch attenuation. When the table height was modified from 7 cm towards X-ray focus to 17 cm away from the X-ray focus, the SDM corrected its reading within ± 5 %.

Figures 2 and 3 show the scanned irradiated film and the 2D dose matrix reported by the SDM. Differences of 1.5 cm in distances or field size were detected when the C-arm angulations were 0°. But, when the C-arm was rotated, an evident deformation in field shape between the film and the SDM immediately appeared, resulting from the SDM system projecting the X-ray beam on a cylinder surface and the film in a horizontal plane. The maximum AK estimated with the SDM (without couch attenuation) resulted in +22 % compared with film (with table attenuation). Table 1 shows the doses measured with OSL dosemeters when they were located in an irradiated and uniform region.

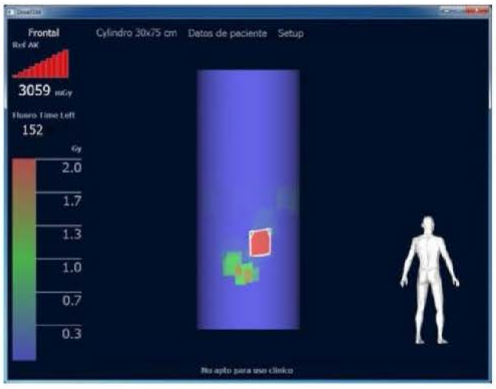

Figure 1. Screen capture of the SDM system. At the upper left corner, the maximum AK value is shown.

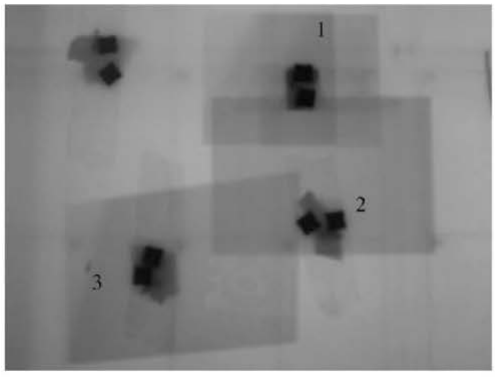

Figure 2. Scanned image of the radiochromic film used during the validation experiment. The OSL dosemeters are marked at positions 1 to 3. Only OSL readings at uniformly irradiated areas were considered.

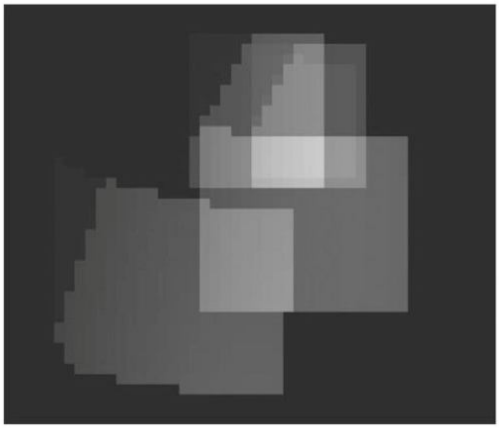

Figure 3. 2D dose matrix provided by the SDM system.

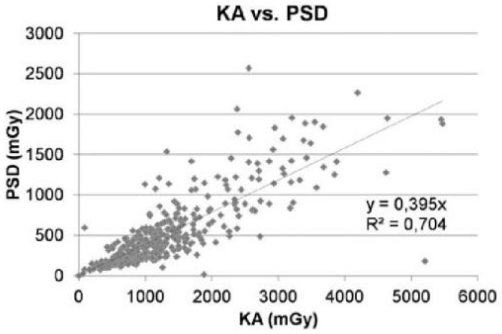

Figure 4. For the 374 patients, the estimation of the PSD is represented versus the AK at the patient entrance reference point.

Table 1. Air kerma measured at points where OSL dosemeters were present.

ROI	OSL (mGy)	SDM (mGy)	Difference (%)
1	1476	1760	19
2	780	1098	40
3	820	777	6

The ROIs are labelled in Figure 2. In the right column, the difference of SDM versus OSL is expressed in %. OSL was affected by couch attenuation. Point 3 was also affected by distance as it was acquired with C-arm rotation.

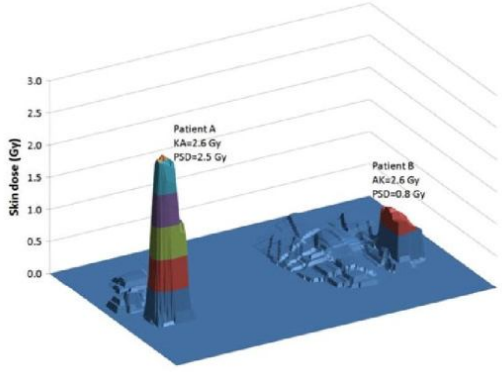

Figure 5. A 3D representation of the dose distribution for two patients with the same AK at patient entrance reference point.

Figure 4 shows the correlation between the AK at the patient entrance reference point and the estimation of the PSD by the prototype for 374 clinical procedures.

DISCUSSION

In this experience, the prototype evaluated did not take into account the couch attenuation; as a consequence, the SDM overestimated the K_i by 22–35 %. But, if the K_i measured was corrected by a BS factor of $\sim 1.35 \pm 0.05$ for ICRU tissue and the beam qualities considered in this experiment[3], the SDM system would estimate the entrance surface AK in patient skin within ± 10 %. Additionally, the geometrical accuracy without any C-arm rotation was estimated within ± 1.5 cm, but the highest geometrical uncertainty comes from the patient geometrical simulation model selected. In this context, uncertainty can be considered acceptable because the main purpose of measuring and showing skin dose distribution in real time is to adequately manage radiation doses during procedures, to determine whether, at the end of the procedure, information about any possible occurrence of skin radiation injuries should be provided to the patient or his/her relatives and eventually to schedule a clinical follow-up. Some other prototypes have investigated these inaccuracies on several patient geometrical models[12], reporting uncertainties of 8–20 % for an elliptical phantom, and 7–15 % for a patient-dependent model obtained from a phantom library.

After plotting the PSD estimation versus AK at the patient entrance reference point (Figure 4), one can notice that in cases of high AK (≈3 Gy), the PSD ranges from 1 to 2 Gy. This reinforces the need for calculating the PSD for cases with high AK or KAP. Figure 5 shows the skin map of two patients with the same AK in the reference point (2.6 Gy), but maximum AK of 2.5 and 0.8 Gy resulted from two very different dose distributions. The level of scatter dose and the impact on occupational doses of all these optimisation strategies are also being considered in this project.

CONCLUSIONS

In IC procedures, AK at the patient entrance reference point or KAP alone are not sufficient to accurately derive PSD, and all the beam projections are needed for a more precise estimation. The SDM prototype gives useful and fairly acceptable information about the patient skin dose: it provides real-time skin dose distributions and helps clinicians to prevent or minimise skin injuries by optimising clinical procedures. It is also proving useful as training material.

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8.4 TRABAJO VI

Dosis ocupacionales en cristalino en cardiología intervencionista. Un estudio multicéntrico.

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Occupational eye lens doses in interventional cardiology. A multicentric study

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Abstract

New European regulation regarding radiological protection of workers and more specifically the new occupational dose limit for the eye lens recently reduced to 20 mSv yr^{-1} may affect interventional cardiologists. This paper presents a set of measurements of occupational doses performed in five interventional cardiology centres and then compared with the new dose limit.

The measurement of occupational doses was performed over the apron at chest level using electronic dosemeters recording $H_p(10)$. In one of the centres, scatter dose at goggles was also measured with optically stimulated luminescence dosemeters calibrated in terms of $H_p(0.07)$.

An average $H_p(10)$ over the apron of 46 μSv/procedure was measured for cardiologists. Lower doses were noted in other professionals like second cardiologists, nurses or anaesthetists. Procedures for valvular and other structural heart diseases involved the highest occupational doses, averaging over 100 μSv/procedure. Important differences in occupational doses among centres may be indicative of different radiation protection habits.

0952-4746/16/010133+11$33.00

The new occupational dose limit for the eye lens is likely to be exceeded by those among the interventionalists who do not use protection tools (ceiling suspended screen and/or goggles) even with standard workloads.

Keywords: radiological protection, interventional cardiology, occupational dose, eye lens

(Some figures may appear in colour only in the online journal)

Introduction

Interventional cardiology (IC) procedures are essential to diagnose and treat several cardiac diseases, but the use of ionizing radiation entails risks for patients and professionals that, although balanced by the benefits produced, must be evaluated and minimized. In the case of professionals involved in IC, current investigations provide evidence of interventionalists' eye lenses radiation injuries [1–4]. Those findings are consistent with the latest epidemiological investigations [5–7] that suggest a dose effect threshold of less than 1 Gy for cataract formation. Another concern among interventionalists is that radiation brain doses might be related with brain tumours in interventionalists [8–10]. There is currently no epidemiological evidence of brain tumours related to low radiation doses, but an excess relative risk of stroke has been identified with doses exceeding 500 mSv and high latency periods [11]. The International Commission on Radiological Protection (ICRP) has reviewed all the epidemiologic evidences, and suggested a dose threshold of 0.5 Gy for cataract formation, proposed a revision of the recommended dose limit for workers' eye lens and reduced it from 150 mSv per year to 20 mSv averaged over 5 years, with no more than 50 mSv in one year [12]. Finally, the European Commission has recently incorporated this ICRP recommendation in its new Council Directive on radiation safety standards [13]. Therefore, the new legislation affects IC workers in the European Union. ICRP has also established a threshold dose of 500 mSv above which cerebrovascular diseases may occur [12]. Consequently, these updates and the ever-growing complexity of IC practices, now including structural cardiology procedures [14], require a periodic evaluation of IC workers' occupational radiation doses, with special attention to eye lens and brain.

The best way to investigate radiation doses received by IC workers would be to analyse their personal dosimetry records, but eye lens dose measurements require a specially designed dosemeter to be worn near the eye. ICRP recommends to wear a second personal dosemeter over the apron to estimate the radiation dose of unprotected organs (like eye lenses) [15], but much too often, IC workers wear only one dosemeter under the apron and even the use of any personal dosemeters is still not widespread among interventional cardiologists [15–18]. Such factors make it difficult in practice to estimate the real doses received by the eye lenses. That is why additional investigations consisting in mathematical and phantom simulations, and measurements during clinical procedures have to be carried out to complement the knowledge of staff doses [19–23]. Results have shown that, depending on the level of protection, many physicians could exceed the new occupational limit for the eye lens and are likely to suffer from radiation-induced cataracts after working for several years without proper protection.

The purpose of this paper is to present personal dose equivalent $H_p(10)$ measured at chest over the apron and collected at five hospitals in IC professionals and to compare it with the new occupational dose limit for the eye lens. Patient's dose area product (DAP) is compared with the readings of the personal dose measured at clinicians' chest over the apron and from dosemeters located at the C-arm. Comparisons between centres and different procedures are

Figure 1. Electronic dosemeters located over the lead apron (left) and also at C-arm (right).

presented. The correlation between $H_p(10)$ measured at chest level and $H_p(0.07)$ measured at the left side of the goggles is also analysed.

Methods

The multicentre and multidisciplinary group DOCCACI (acronym for dosimetry and quality criteria in IC in Spanish) was formed to investigate the radiation doses received by patients and staff in IC [24, 25]. Five hospitals belonging to this workgroup have measured $H_p(10)$ over the apron in their own catheterization labs. The total number of catheterization laboratories included in this study was 10. Some of these centres are university hospitals with fellows in training. Personal doses have been measured with real time electronic dosemeters worn by interventional cardiologists, nurses and other clinical specialists like technologists or anesthesiologists. The DoseAware system (Philips Medical Systems, Best, The Netherlands) was used: it consists of small solid-state detectors measuring 3.5×3.5 cm, specially designed to measure personal doses in interventional rooms [26]. Following the ICRP recommendations, the readings of these dosemeters, worn over the apron (figure 1), were used to estimate the dose at eye lenses (in situations where no goggles were worn) [14]. The correlation between the eye lens dose and the $H_p(10)$ measured over the apron has been studied by several investigators [27–30]. This correlation is affected by several variables like the beam quality, the angular response of the dosemeter, the operator position, the C-arm angulation, the use of goggles and the position of non-structural shielding. All these variables provide a high dispersion in the relationship between these two magnitudes, but on average, the $H_p(10)$ or $H_p(0.07)$ tend to overestimate the dose at eye lenses and can be interpreted as conservative estimation [29, 30] for pragmatic and practical operational radiation protection purposes in cardiology laboratories. The electronic dosemeters are linked wireless to a base station which stores readings of $H_p(10)$ cumulative personal dose equivalent and dose rate values every second. The values can be displayed in real time during the interventions on a screen installed for this purpose inside the interventional room and thus readily accessible to the professionals, but during this survey, the screen was hidden to avoid influencing interventionalists in their protection habits. The x-ray unit provides dose reports that allow professional doses to be identified for each single procedure and related to patient doses. For each procedure, personal dosemeters were located over the apron at chest level and one of the dosemeters was located at the inferior

part of the C-arm, forming approximately a 45° degree angle with the horizontal line as shown in figure 1. A conservative estimation of the scatter cumulative dose per procedure was measured with the C-arm dosemeter, when no protection was used [31]. The manufacturer certificates the performance of these dosimeters in terms of deviation in linearity <20% between 40 μSv h^{-1} and 300 mSv h^{-1}, the energy response <20% within N-40 and N-100 and angular dependence <30% within 50°. The performance of these dosemeters has been tested with pulsed beams in interventional laboratories and differences of less than 15% in cumulative dose against thermoluminescece dosemeters (TLD) were deemed acceptable [32].

In one of the centres, and for a limited number of procedures, the scatter dose was also measured on the external left side of the goggles with small size (1 × 1 × 0.2 cm) optically stimulated luminescence dosemeters (OSLD) model nanodot (Landauer Inc.). These passive dosemeters, similar to TLD, have proved well suited to measure personal doses in interventional practices [33]. Thanks to their small size, they can easily be attached to protection glasses. They were calibrated to measure $H_p(0.07)$ at Institut de Tècniques Energètiques (Barcelona, Spain), an accredited secondary laboratory.

$H_p(10)$ over the apron were measured during coronary angiographies (CA) and CA with ad hoc percutaneous coronary interventions (PCI). In one of the centres, patient and personal doses were also recorded during PCI of total chronic occlusions (CTO), valvular procedures including valvular replacements and leakage closures, other structural procedures such as aortic prosthesis, foramen ovale and interventricular closures and electrophysiology procedures like pacemakers and ablations. In each centre, occupational doses during interventions were measured sequentially without any selection criteria. Cardiologists, nurses and in some cases anaesthesiologists carried electronic active personal dosemeters. Information regarding the access site (femoral or radial artery) was recorded and so was the DAP delivered to the patient. All participants declared to routinely use ceiling suspended screen.

The statistical analysis was carried out with SPSS v12.

An independent local Ethics committee approved this study under the title 'dosimetry and quality criteria in IC' (code 15/007-E).

Results

Personal doses over the apron were measured individually in a total of 699 procedures. All centres had similar contribution to sample size regarding CA and PCI, but as to CTO, valvular, structural and electrophysiology, most data (>80%) were provided by Centre 10. Radial access was performed in most procedures (≥90%), except in one centre (10 in table 1) that only performed radial access in 26% of its procedures. Table 1 shows the average personal doses for the different professionals in the different centres. Among the professionals, the first cardiologist is the most exposed one for standing closest to the patient. The distance between the cardiologist and the patient varies from 0.7 to 1 m approximately depending on the procedure and the access site selected (femoral or radial). The second cardiologist usually stands at the first cardiologist's right side and therefore far from the patient. Depending on their task, nurses usually stay at the cardiologists' right side or move around the room to handle instruments to the physicians or monitor the patient throughout the procedure. Other staff like anaesthesiologists who do not need to stand close to the patient try to keep at a proper distance from the radiation source. Echocardiography specialists are the exception, as in occasions they have to stand very close to the patient to manage the ultrasound probe and in so doing, occasionally receive high dose rates. The average dose measured over apron per procedure resulted in 46 μSv for the first cardiologist, being CA and PCI the most frequent

Table 1. For each centre, the number of procedures measured, the average patient dose, and average $H_p(10)$ over the apron for interventional cardiologists, nurses and other medical professionals like anaesthesiologists or ultrasound specialists. University hospitals with fellows participating in procedures are marked with$^{(U)}$. At centre 10, the dose for the group 'Others' had a small sample size ($N = 14$) with two cases of high dose.

Centre	N	DAP (Gy·cm^2)	Cardiologist 1	Cardiologist 2	Nurse	Other	C-Arm
10$^{(U)}$	285	96	66	38	15	171	930
20$^{(U)}$	97	95	46	19	14	18	951
30$^{(U)}$	98	69	31		7	3	617
50$^{(U)}$	76	53	23	16	7	40	459
100	143	41	28		7	51	289
Average		76	46	28	12	35	704

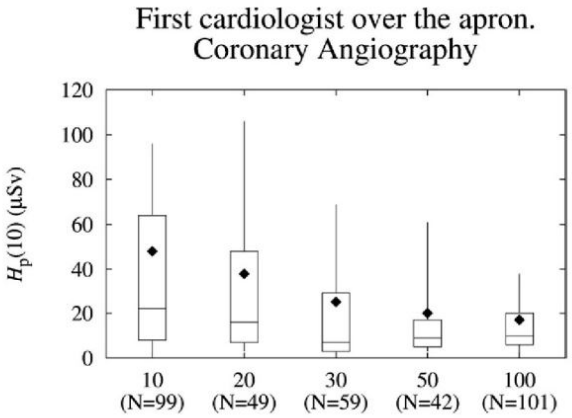

Figure 2. Over the apron dose for the first cardiologists during CA and for the different centres. With bars and sticks the percentiles 10, 25, 50, 75 and 90 and with diamonds the average. In brackets and underneath the centre id, the sample size.

procedures (88%). The maximum dose of 1200 μSv during a procedure was that received by an ultrasound specialist. In 10% of the procedures, doses recorded were above 100 μSv. Figure 2 shows the average and main percentiles (p_{10}, p_{25}, p_{50}, p_{75} and p_{90}) of the occupational dose during CA procedures for the first cardiologists at different centres. Figure 3 shows the average and main percentiles of personal doses classified according to the type of procedure for the first cardiologist at Centre 10. There were 120 $H_p(0.07)$ readings recorded at the goggle outer left side with OSLD (obtained from centre 10) and then compared with the $H_p(10)$ over the apron chest readings from electronic dosemeters. Linear regression resulted in dose-at-goggles = 0.6·dose-at-chest. The Pearson correlation was moderate $r^2 = 0.59$, but statistically significant ($p < 0.001$). However, when analysing the main statistics, similar figures were obtained in average values (35 versus 44 μSv) and median ones (21 versus 21.5 μSv) among goggle and chest readings. In figure 4, the graph on the left shows the correlation between patient DAP and the C-arm dosemeter and the graph on the right the correlation between DAP and the cardiologist's dosemeter.

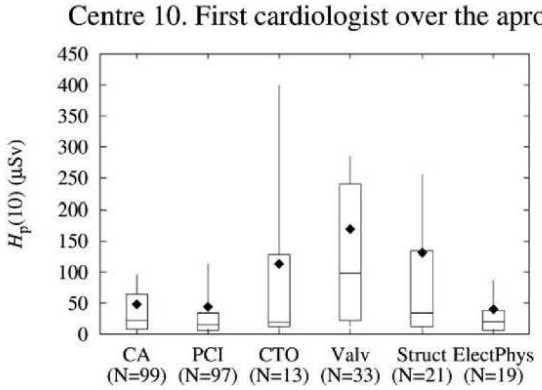

Figure 3. For Centre 10 and classified by procedures, with bars and sticks the percentiles 10, 25, 50, 75 and 90 and with diamonds the average of the first cardiologist personal dose over the apron at chest level. In brackets and underneath the procedures, the sample size.

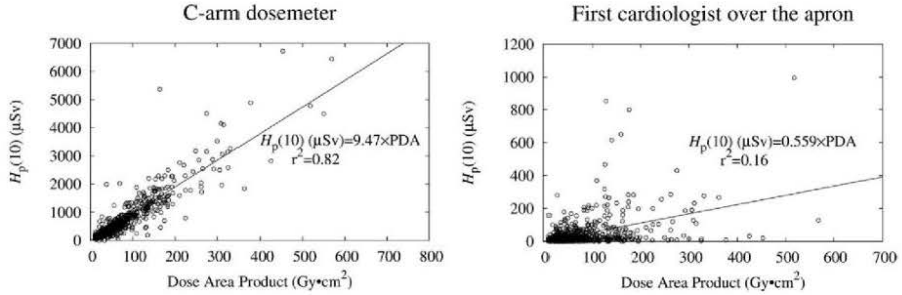

Figure 4. Left: C-arm dosemeter readings (microSv) versus patient's dose area product. Right: cardiologist dosemeter readings (microSv) versus dose area product.

Discussion

Correlation between chest and googles readings

From the 120 readings obtained at centre 10, the relationship found between $H_p(0.07)$ measured on the external left side of the goggles with small OSLD and $H_p(10)$ at chest level with electronic dosemeters showed that the average dose at goggle level can be estimated conservatively as 20% lower than the average dose measured at chest level. The linear regression analysis indicated statistically significant correlation. Farah *et al* [28], in their phantom investigation about correlation between $H_p(3)$ in eye and $H_p(10)$ in chest and collar, pointed out an average relation of 0.7 between eye dose and $H_p(10)$ in chest left side when investigating cardiology procedures. The relationship between both quantities is complex, with multiple variables involved like beam quality, dosimeter position or beam incidence relative to operator position, and results in important uncertainties (≥40%). The differences between $H_p(0.07)$, $H_p(3)$ and $H_p(10)$ are of less importance for these beam qualities than the geometric position of the dosimeters. Vanhavere *et al* [23], have reported differences of about 5% between

$H_p(0.07)$, $H_p(3)$ for N-60 and N-80 beam qualities. Between $H_p(3)$ and $H_p(10)$ differences are expected to be slightly higher. As pointed out by Farah *et al* [28], the most accurate method to measure eye lens dose would be to locate the $H_p(3)$ dosemeter near the eye, but this proves too complicated in clinical practice and is the facto limited to cases with operators with eye doses close to or higher than the limit. Locating the dosemeter at chest or collar level (as suggested by ICRP) can also offer another practical alternative in cases of restrospective measurements, epidemiological studies or professionals with doses far below the limit: this approach can, despite its limitations, offer useful information about eye lens doses.

$H_p(10)$ measured at workers chest over the apron

The values obtained in this survey are of the same order of magnitude as the ones reported by the European research group (ORAMED) for CA and PCI, i.e. 50 μSv/procedure [23]. In view of the fact that the ceiling suspended screen was used in this survey, the doses recorded can be regarded as significant compared to the new limit of 20 mSv yr^{-1}, recently included in the new European Directive [13]. If we consider that the average dose per procedure in table 1 is 46 μSv and we correct it by a factor of 0.8 (as it was measured at chest level), it would take a workload of more than 550 procedures yr^{-1} without goggles to exceed the new legal limit. If goggles were used, doses at eye lenses could be reduced by a factor ranging from 1.6 to 7 depending on the design of the glasses and the room layout [15, 19, 34, 35]. But if both goggles and the ceiling suspended screen were not used, the limit could easily be exceeded even with low workloads. The highest average personal dose (twice the value of Centre 50) was measured at Centre 10 (table 1 and figure 2). This may mainly be attributed to the greater fraction (24%) of complex procedures, such as CTO and structural procedures in its sample, consequently leading Centre 10 to deliver greater average doses to patients. In this centre, there were also a greater number of fellows actively involved in procedures. For instance, the valvular procedures, recorded mainly at centre 10, required average and median values higher than 100 μSv/procedure for the first cardiologist. As a result, the increasing complexity of practices implies consequences on occupational doses that could entail appropriate radiological protection measures. The analysis of CAs on their own also revealed the highest personal doses at Centre 10, which points out how important the differences in protection habits can be between centres. In the case of Centre 10, the high number of fellows may be the reason for such differences.

In the case of nurses, from the 850 readings measured during the 699 procedures of this survey, the average doses recorded were almost 4 times lower for nurses than for the first cardiologist. Taking the 12 μSv per procedure obtained in this survey as average dose, 1600 procedures per year would be necessary to exceed the new dose limit. But the doses received by nurses may vary: depending on the procedures and the role the nurses undertake in them, the nurses'position and the possibility they have of using either distance or the shielded screen may be quite different. Nurses could occasionally be delivering drugs to patients while the physician is acquiring fluoroscopy or cine images, which may result in sporadic high dose rates being recorded. Some papers reported high doses in nurses [3, 4] in cases where radiation protection was neglected: nurses should thus constantly bear in mind the importance of minimal radiation protection rules to avoid such high personal doses. Other medical personnel, like ultrasound specialists, who in some cases have received doses higher than the first cardiologist, need close surveillance and counselling regarding their protection and their workload. As a result, in table 1 and at centre 10, in the box 'other medical personnel', the small sample size ($N = 14$) along with two very high dose values (>700 μSv) in valvular procedures resulted in an average personal dose higher for these specialists than for the first cardiologist.

$H_p(10)$ measured at the C-arm

With the dosemeter at C-arm located on the lower part of the x-ray tube, in the surroundings of the patient backscatter radiation and with no protection barrier like a ceiling suspended screen, information could be obtained about the level of scatter radiation in the worst-case geometry. High correlation ($r^2 = 0.82$) was observed (figure 4) between patient DAP and C-arm dosemeter readings. With the dosemeter located on the first cardiologist's chest, the operator's dose per unit of patient dose was expected to be lower, as the dosemeter was moved away from the area where patient backscatter was predominant. Depending on the C-arm angle, this reduction was estimated in a factor of 3 (AP), 2 (LAO 45°) or 5 (CRAN 30°) [31]. In addition, when the ceiling suspended screen is used, an additional reduction in the slope (personal dose per unit of patient dose) of the order of the screen attenuation factor should be observed. Such screen attenuation factor, depending on the beam quality, could range from 20 to 50 or even higher [2]. In this sample, as shown in figure 4, the C-arm dosemeter recorded 9.47 μSv $(\text{Gy}\cdot\text{cm}^2)^{-1}$ and the first cardiologist dosemeter recorded 0.56 μSv $(\text{Gy}\cdot\text{cm}^2)^{-1}$. The reduction in personal dose per patient dose was then a factor of 17, which is inferior to the reduction obtained with the use of the protection screen only, and the correlation ($r^2 = 0.16$) between the patient and the cardiologist dose was lost. Such results might arise from an irregular use of protection screen, despite cardiologists' assertions to the contrary. Protection ceiling-suspended screens normally provide 0.5 mm of lead equivalent thickness, with high attenuation properties to scatter beams in interventional practices and can, as mentioned above, attenuate from 95 to 99% of the scatter radiation, depending on the beam quality. If the protection screen was located correctly over the patient, it would provide the best protection for the eye lens in interventional practices. The majority of protection glasses models have an equivalent lead thickness of 0.75 mm: such thickness in protective glasses could be thought to reduce eye lens radiation dose better than protection screens. But it has been demonstrated [34, 35] that the maximum dose reduction achievable by wearing goggles is limited by radiation leaks through the goggles and the contribution of scatter radiation inside the operator's head. So, despite a higher lead equivalent thickness in goggles, the dose reduction factor measured was below 10 in experiments and even lower in clinical use [15, 19, 34, 35]. It is even worth noting that in some circumstances (high workloads and inefficient goggle design), the only use of goggles may not, in absence of a protective screen, be enough to keep eye lens doses under the occupational dose limit. A protective screen correctly positioned can, on the contrary, help reduce eye lens doses and what is more, the dose to the whole brain, head and thyroid gland.

The value of 46 μSv/procedure may be representative of the average scatter dose for those professionals that use the protection screen and have a standard workload mainly composed of CAs and ACTPs. This average value will be higher for those professionals who perform more complex procedures as ACTPs with chronic total occlusions or structural procedures. Provided that the protection screen is used, assuming that the average dose of 46 μSv/procedure could be representative of the external scatter dose to the head and depending on the workload and procedures, a professional is unlikely to receive more than 500 mSv in brain (the threshold dose when cerebrovascular effects may occur) during his professional life. On the contrary, if no protection screen is used, the average value of 700 μSv/procedure registered on the C-arm dosemeter is deemed to be more representative of the dose received by some parts of the head (corrected by a factor 1/3 for geometry reasons). The brain is likely to receive 500 mSv in less than fifteen years' work with a standard workload of 450 procedures yr^{-1}. For those cardiologists who perform complex procedures, the threshold dose of 500 mSv in brain could be reached in even less time.

Conclusions

Personal dose equivalent $H_p(10)$ recorded at operators' chest level (over the apron) in cardiac catheterization laboratories can be used to roughly estimate eye lens doses when eye dosemeters are not available. When an accurate eye dosimetry is needed, dosimeter specially designed to measure $H_p(3)$ at the eye will be more appropriate. The level of doses measured shows that personal surveillance of eye lens dose is of major importance for cardiologists. If professionals use the protective screen and goggles, the new European occupational dose limit is unlikely to be reached, but if they neglect personal protection, this limit can be exceeded even with moderate workloads. To reduce eye lens doses, the best option is to keep patient doses as low as possible and to correctly use the ceiling suspended screen. Goggles are also of help to reduce eye lens dose. If the protection screen is not used, the doses received by the brain can be significant too. The ceiling suspended screen offers the additional advantage of protecting the whole brain from scatter radiation.

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Conflict of interest

The authors have no conflicts of interest to declare.

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8.5 TRABAJO V

Estimación de la dosis en cristalino durante procedimientos intervencionistas. Comparando cardiología neurorradiología y radiología intervencionista.

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ESTIMATION OF STAFF LENS DOSES DURING INTERVENTIONAL PROCEDURES. COMPARING CARDIOLOGY, NEURORADIOLOGY AND INTERVENTIONAL RADIOLOGY

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The purpose of this article is to estimate lens doses using over apron active personal dosemeters in interventional catheterisation laboratories (cardiology IC, neuroradiology IN and radiology IR) and to investigate correlations between occupational lens doses and patient doses. Active electronic personal dosemeters placed over the lead apron were used on a sample of 204 IC procedures, 274 IN and 220 IR (all performed at the same university hospital). Patient dose values (kerma area product) were also recorded to evaluate correlations with occupational doses. Operators used the ceiling-suspended screen in most cases. The median and third quartile values of equivalent dose *Hp*(10) per procedure measured over the apron for IC, IN and IR resulted, respectively, in 21/67, 19/44 and 24/54 μSv. Patient dose values (median/third quartile) were 75/128, 83/176 and 61/159 Gy cm^2, respectively. The median ratios for dosemeters worn over the apron by operators (protected by the ceiling-suspended screen) and patient doses were 0.36; 0.21 and 0.46 μSv Gy^{-1} cm^{-2}, respectively. With the conservative approach used (lens doses estimated from the over apron chest dosemeter) we came to the conclusion that more than 800 procedures y^{-1} and per operator were necessary to reach the new lens dose limit for the three interventional specialties.

INTRODUCTION

Since the statement of the International Commission on Radiological Protection (ICRP) on tissue reactions (deterministic effects) issued in April 2011[1], several regulatory initiatives and scientific activities have been launched to improve patient and staff radiation safety and to foster optimisation actions in interventional radiology. The ICRP alerted the radiological community to the epidemiological evidence and pointed out some tissue reaction effects when threshold doses are or might be lower than previously considered: 0.5 Gy for the lens of the eye (radiation-induced opacities) and also 0.5 Gy for circulatory disease of the heart or brain. Exposure of staff (lens of the eye) and patients to doses of this magnitude could be reached during complex interventional procedures and the ICRP recommended particular emphasis be placed on dose optimisation in these circumstances[2].

For occupational exposure, the ICRP recommended an equivalent dose limit for the lens of the eye of 20 mSv y^{-1}, averaged over defined periods of 5 y, with the dose in a single year not exceeding 50 mSv. The immediate consequence was a change in the international basic safety standards (BSS)[3] and in the European BSS and the adoption of the new limit[4].

Many of the recent results on lens dosimetry in professionals working in the medical area (especially in fluoroscopy guided procedures) were obtained during the European ORAMED program. Domienik *et al.*[5] reported results obtained in interventional cardiology and interventional radiology facilities in 34 European hospitals. They found that the highest eye lens doses were measured during embolisations and concluded that it is difficult to find a general correlation between kerma area product (KAP) and extremity or eye lens doses.

Vanhavere *et al.*[6] reported the final results of the ORAMED project for eye lens doses in interventional radiology and cardiology (using thermoluminescent dosemeters and plastic bags). The median values of eye doses were <40 μSv per procedure and the ratio between eye doses and KAP for cardiac procedures were 0.7 μSv Gy^{-1} cm^{-2}. This value is indicative of the use of a ceiling-suspended screen in most of the measured procedures. Vanhavere *et al.* concluded that with an annual dose limit of 20 mSv for the lens of the eye, many physicians could exceed the limit.

Vano *et al.*[7] reported initial experience on the use of active personal dosemeters with a real-time display inside the catheterisation rooms of cardiology and interventional radiology laboratories. A comparison with thermoluminescent passive dosemeters was made, and the results were satisfactory[8].

The ISEMIR[9] Working Group on Interventional Cardiology has produced a set of recommendations for occupational radiological protection and concluded, after a wide international survey, that the dose received by cardiologists during percutaneous coronary interventions, electrophysiology procedures and other interventional cardiology procedures can differ by more than an order of magnitude for the same type of procedure and for similar patient doses.

The purpose of this article is to estimate lens doses using over apron active personal dosemeters on a

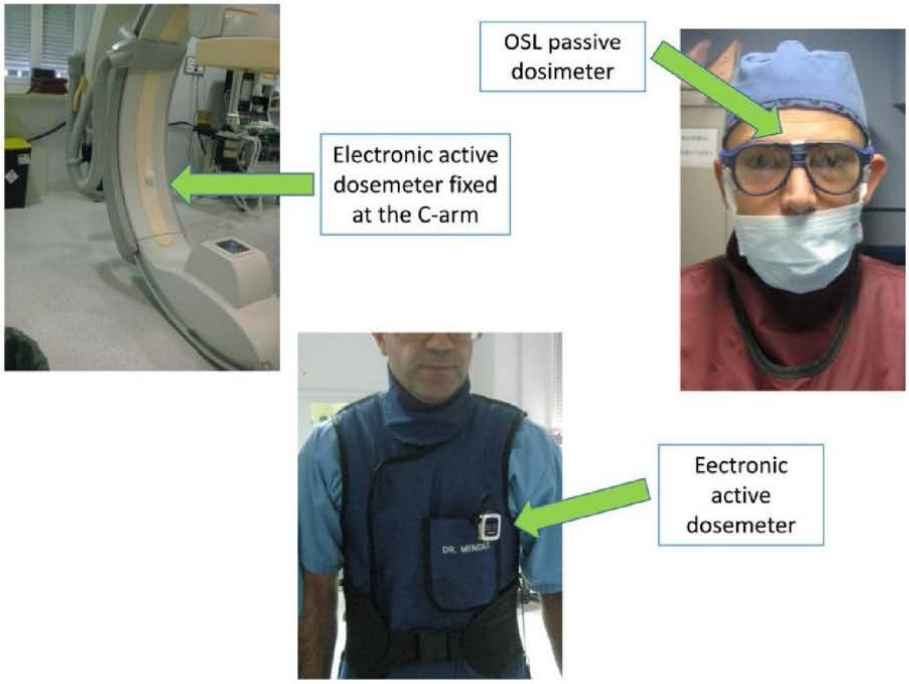

Figure 1. Position of the active and passive dosemeters to estimate lens doses and scatter dose at the C-arm. OSL, optically stimulated luminiscent dosemeters.

Table 1. Summary of statistical descriptors of the measured values.

	C-arm dose per procedure/ μSv	Over apron dose per procedure/ μSv	Patient dose per procedure/ Gy cm^2	μSv at the C-arm per Gy cm^2	microSv staff over apron per Gy cm^2)
Cardiology (204)					
Mean	982	65	96	10.7	0.84
Standard deviation	928	131	79	4.5	1.65
Median	**682**	**21**	**75**	**9.6**	**0.36**
Third quartile	1298	67	128	12.1	0.95
Maximum	5370	995	550	32.8	14.6
Neuroradiol. (274)					
Mean	1103	46	136	8.2	0.38
Standard deviation	1211	82	147	1.6	0.46
Median	**646**	**19**	**83**	**8.3**	**0.21**
Third quartile	1470	44	176	9.2	0.44
Maximum	9650	558	1112	13.3	3.5
Interv. radiol. (220)					
Mean	764	57	105	9.7	2.6
Standard deviation	921	102	130	4.6	4.5
Median	**449**	**24**	**61**	**8.1**	**0.46**
Third quartile	1120	54	159	12.3	3.3
Maximum	6490	726	902	36.9	33.8

Median values are highlighted in bold.

sample of individual procedures in interventional catheterisation laboratories (cardiology IC, neuroradiology IN and radiology IR), to evaluate correlations between estimated lens doses and patient doses for the three interventional specialties and to evaluate if, with the typical workload, the new dose limit to the lens of the eyes would be reached if professionals systematically used the radiation protection tools and followed the protection rules.

MATERIALS AND METHODS

Active electronic personal dosemeters (DoseAware system from Philips) placed over the lead apron, in the operator's left pocket at chest level (Figure 1), were used in a sample of 204 IC procedures, 274 IN and 220 IR (all performed at the same university hospital). The X-ray systems were Philips Allura with flat detectors, FD10 in the cardiac laboratory, a biplane system FD20/FD10 for the neuroradiology room and FD20 for the interventional radiology laboratory. Another dosemeter was placed in a fixed position at the C-arm of the X-ray system (see Figure 1) to measure the level of scatter radiation.

Patient dose values (kerma area product) were recorded to evaluate correlation with C-arm and lens doses. Operators, all certified in radiological protection, used the ceiling suspended screen in most of the procedures. Available literature mentions a poor correlation between chest dose measurements and eye lens doses during clinical procedures (lens doses being lower than chest doses) but the use of lens dosemeters is problematic in routine practice. Thus, the value measured at the chest, over the apron, is suggested as a conservative approach to estimate lens dose.

Notwithstanding this, in a sub-sample of 120 procedures (only results for interventional cardiology are reported) optically stimulated luminiscent (OSL) dosemeters (duly calibrated to also measure $Hp(10)$) were used at the glasses of the cardiologists (Figure 1) to compare the measured lens dose values with the chest active electronic dosemeter.

RESULTS

Values of equivalent dose $Hp(10)$ per procedure (median/third quartile) measured over the apron for cardiology, neuroradiology and interventional radiology resulted, respectively, in 21/67, 19/44 and 24/54 μSv. The values recorded at the C-arm (45° down from the isocenter plane) were: 682/1298, 646/1470 and 449/1120 μSv. Patient dose values (median/third quartile): were 75/128, 83/176 and 61/159 Gy cm^2. The median values of the ratio between $Hp(10)$ at the C-arm and patient dose values were 9.6, 8.3 and 8.1 μSv Gy^{-1} cm^{-2}. The median ratios for the dosemeters worn by the operators at the chest over the apron (working protected by the ceiling-suspended screen) and patient doses, were 0.36, 0.21 and 0.46 μSv Gy^{-1} cm^{-2} for cardiology, neuroradiology and interventional radiology, respectively.

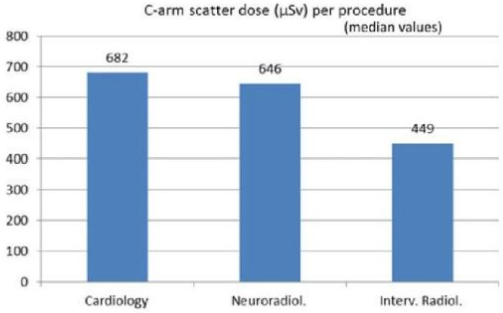

Figure 2. C-arm measured scatter doses (median values) per procedure for the different medical specialties included in the study.

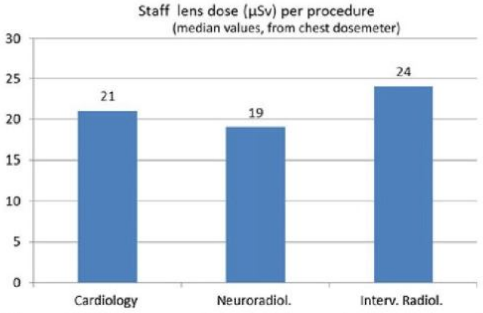

Figure 3. Over apron dose (median values) per procedure for the different medical specialists.

Table 1 presents the global statistical results of the full sample of procedures measured at the IC, IN and IR catheterisation laboratories.

Figure 2 presents the median values of the scatter dose per procedure at the C-arm for the three catheterisation laboratories where the data were collected.

Figure 3 presents the median values of the lens dose estimation from the dose measured by the active electronic dosemeter at the chest of the interventionists, over the lead apron, for the three catheterisation laboratories.

Figure 4 presents the median values of KAP corresponding to the sample of procedures with simultaneous staff dose measurements. Samples correspond to a set of random routine diagnostic and therapeutic procedures.

Figure 5 presents the ratio (median values) of scatter dose at the C-arm ($Hp(10)$), to the KAP of the different procedures.

Finally, Table 2 contains a detailed statistical analysis of the occupational doses per procedure at the

interventional cardiology laboratory, including maximum dose rate values (at the C-arm, at the chest dosemeter of the cardiologists and at the chest of the nurse). Lens doses measured with OSL at the glasses of the cardiologists in a sub-sample of 127 interventional cardiology procedures are also included in this table.

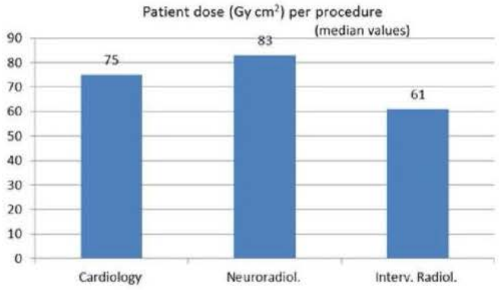

Figure 4. Patient dose per procedure (median values) for the different medical specialties included in the study.

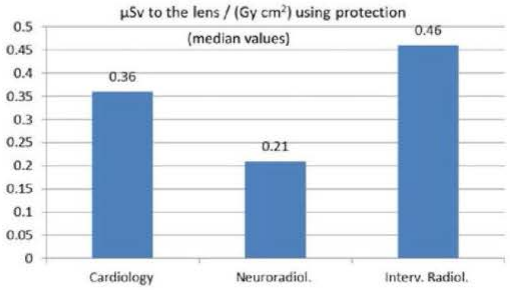

Figure 5. Ratio of over apron doses and patient doses (median values) for the different medical specialists.

DISCUSSION AND CONCLUSIONS

When comparing the three interventional specialties, the present results show that the median values of scatter doses at the C-arm are in the range of a few hundreds of µSv (449–682), being around 50 % higher for cardiology and neuroradiology than for interventional radiology. It should be noted that patient doses (KAP values) in the analysed samples were also lower for interventional radiology. The ratios between scatter dose at the C-arm and the values of KAP resulted about 20 % higher for cardiology (see Table 1: 9.3 µGy Gy^{-1} cm^{-2} for IC and 8.3 for IN and 8.1 for IR).

The median values of $Hp(10)$ measured by the chest dosemeter (over the apron) as recommended by ICRP in 2000 to estimate lens doses[10] resulted in all the cases, in a few tens of µSv per procedure. This means that if professionals work properly protected by the ceiling-suspended screen, the new limit of 20 mSv y^{-1} will not be easily reached. It should nevertheless be highlighted that in this sample, several cases of high lens doses per procedure have been measured. The maximum doses resulted between 550 and 1112 µSv in single procedures, and the mean values of doses per procedure measured by the chest dosemeter resulted (see Table 1) in 65 µSv for IC, 46 for IN and 57 for IR. These values are more than a factor of two higher than the median values, which mean that in many procedures, the ceiling-suspended screen is still not properly used.

Considering the median values of the ratio between lens doses (estimated from the chest dosemeter)

Table 2. Summary of statistical descriptors of the measured values for interventional cardiology.

			Interventional cardiology		
	Cardiol. over apron dose per procedure/ µSv	OSL cardiol. eye dose per procedure/µSv	C-arm dose rate per procedure/ mSv h^{-1}	Cardiol. over apron dose rate per procedure/mSv h^{-1}	Nurse over apron dose per procedure/ mSv h^{-1}
Sample	204	127	197	191	168
Mean	65	50	29	4	2
Standard deviation	131	104	16	6	5
Median	21	**21**	**29**	**2**	**1**
Third quartile	67	39	38	5	2
Maximum	995	696	86	39	41

Median values are highlighted in bold.

and KAP (0.21–0.46 μSv Gy^{-1} cm^2) it could be said that the use of protective screen is 'reasonable' in this sample, but needs some improvement at the IR laboratory.

The statistical results of the 'real' lens dose values measured with OSL resulted very similar to the values registered by the chest active dosemeters (for IC). This supports the recommendation produced by ICRP in 2000[10] to use the over apron dosemeter as a practical approach to estimate the dose to the lens of the eyes. The median values were 21 μSv in both cases (see Table 2), but third quartile was 40 % lower for OSL values. Table 2 also contains data on scatter dose rates, the maximum values being around 40 mSv h^{-1} for cardiologists and also for nurses (due to operating positions during procedures which do not allow protection). The median values are much lower (2 and 1 mSv h^{-1} for cardiologists and nurses, respectively).

In any case we should highlight the limitation of the results in this article due to that we are estimating lens doses from the values measured by the over apron dosemeter and more experimental data will be needed in the future to suggest better correlations[11].

As a conclusion, with the median values of Hp(10) measured with over apron dosemeters for the three interventional specialties, more than 800 procedures per year and per operator were necessary to reach the new lens dose limit, with the conservative approach used to estimate lens doses from the over apron chest dosemeter. This value should be around 400 procedures if the mean values were used for this extrapolation. But the maximum and mean values measured suggest the need for a better use of the ceiling-suspended screen or for goggles in some complex procedures. When the correlation between estimated lens doses and patient doses was investigated, differences of 133 % were found between the different specialties, with the highest value in interventional radiology.

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